# IN THE UNITED STATES COURT OF FEDERAL CLAIMS
# OFFICE OF SPECIAL MASTERS
**No. 12-423V**
**Filed: September 21, 2015**

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| MARY KATE WRIGHT and GARRY WRIGHT, as legal representatives of a minor child, M.W., Petitioners, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent. | * | Table Encephalopathy; Postvaccinal Encephalopathy; Acute Encephalopathy; Chronic Encephalopathy; Severity Requirement; Corroboration of Testimony |

*Mindy Michaels Roth, Britcher, Leone & Roth, LLC, Glen Rock, NJ, for petitioners.*
*Lara Ann Englund, U.S. Department of Justice, Washington, DC, for respondent.*

## RULING ON ENTITLEMENT[1]

**Vowell,** Special Master:

On June 28, 2012, Mary Kate Wright and Garry Wright ["Mrs. Wright," "Mr. Wright" or "petitioners"] filed a petition on behalf of their minor child, M.W., for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq*. [the "Vaccine Act" or "Program"].[2] The petition alleged that the Pentacel vaccine (the trade name for a vaccine consisting of combined diphtheria, tetanus, and acellular pertussis ["DTaP"], inactivated polio virus ["IPV"], and the Haemophilus influenzae type B ["Hib"] vaccines) M.W. received on July 6, 2009 caused seizures and subsequent encephalopathy. Petition at 1.

[1] Because this ruling contains a reasoned explanation for my action in this case, it will be posted on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire decision will be available to the public.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012)

To prevail under the Vaccine Act, a petitioner must prove either a "Table" injury[3] or that a vaccine listed on the Table was the cause in fact of an injury (an "off-Table" injury). While the DTaP, IPV, and Hib vaccines are listed on the Vaccine Injury Table, only the DTaP vaccine is associated with the Table injury of "encephalopathy."[4] The petition's first paragraph asserted that, within hours of the administration of the DTaP-containing vaccine, M.W. "suffered from seizures and subsequent encephalopathy as set forth in the 'Table.'" Paragraph 74 of the petition alleged that M.W. "suffered an encephalopathy and an autism spectrum disorder, which was caused-in-fact by the Pentacel vaccination." At the hearing, petitioners proceeded under both the Table injury and the causation in fact claim.

The issue of whether M.W. experienced a Table encephalopathy after his Pentacel vaccination is an extremely close call. Based on the facts of this case, the definitions in the Qualifications and Aids to Interpretation ["QAI"] section of the Vaccine Injury Table,[5] and the opinions of the testifying experts and M.W.'s physicians, I conclude that petitioners presented preponderant evidence that M.W. experienced a seizure accompanied by brief loss of consciousness shortly after his receipt of a pertussis-containing vaccination, and an acute encephalopathy which lasted for more than 24 hours thereafter, and the postvaccinal changes in behavior displayed thereafter qualified as a chronic encephalopathy persisting for more than six months. Although there was some evidence suggesting that M.W. was ill prior to receipt of the Pentacel vaccination, such evidence did not rise to the level of alternate cause. Similarly, M.W.'s behavior prior to the vaccination may have included some symptoms suggestive of atypical development, but the presence or lack of such behaviors (which do not constitute symptoms of an encephalopathy) does not affect a determination that M.W. experienced an acute encephalopathy followed by a chronic encephalopathy.

M.W.'s current diagnoses include an autism spectrum disorder ["ASD"].[6] Some of the behavioral symptoms of this disorder constitute the persisting encephalopathic

[3] A "Table" injury is an injury listed in the Vaccine Injury Table (42 C.F.R. § 100.3 (2011)), corresponding to the vaccine received within the time frame specified.

[4] *See* 42 C.F.R. § 100.3(b)(2). The Table definition of "acute encephalopathy," is more restrictive than the common medical meaning of the term. Encephalopathy is defined very broadly as "any degenerative disease of the brain." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY ["DORLAND'S"] (32d ed. 2012) at 614. An encephalopathy may be static or progressive.

[5] See 42 C.F.R. § 100.3(b). The QAI section of the Vaccine Injury Table, 42 C.F.R. § 100.3(b), contains definitions for the terms used in the Table. *See Althen v. Sec'y, HHS*, 58 Fed. Cl. 270, 280 (2005), *aff'd*, 418 F.3d 1274 (Fed. Cir. 2005) (noting that the QAI should be used to interpret key terms found in the FTable).

[6] Respondent's expert, Dr. Max Wiznitzer, defined an autism spectrum disorder as a neurodevelopmental disorder that manifests with significant impairments in socialization and social communication and with restricted interests and repetitive behaviors. Transcript ["Tr."] at 328-29. Those with ASD have "qualitative differences in how they interact and how they use their language to interact in a social manner," with "language" including "both verbal and nonverbal abilities." Tr. at 329. They also have "an exaggerated manifestation of typical childhood behaviors, such as opening and closing doors, playing

condition necessary to satisfy the remainder of the Table injury requirements—that a chronic encephalopathy persist for at least six months and include symptoms persisting from the acute encephalopathy.

*This is not to say that the vaccine was the actual cause of M.W.'s ASD or of any symptom of M.W.'s ASD. This decision should not be construed as holding that a vaccine can or does cause ASD.*

The legislative scheme that created Table injuries established a presumption of causation that obviates any need for an actual causation determination. Congress established the Table with full knowledge that applying the Table definitions would result in compensation for some injuries not truly vaccine-caused. H.R. REP. 99-908, 18, 1986 U.S.C.C.A.N. 6344, 6359.[7] *See also* Tr. at 326, 375-76 (Dr. Wiznitzer's discussion concerning the compensation of individuals for a Table injury at an earlier time in the existence of the Vaccine Program who were later determined to have Dravet's syndrome (a genetic condition unrelated to vaccination)).

However, because petitioners presented actual causation evidence, I address that evidence very briefly here. Had it been necessary to determine actual causation in this case, petitioners would have failed to meet their burden. Doctor Yuval Shafrir's opinion that M.W. sustained an autoimmune reaction (that, is, an antibody response) to Pentacel within an hour or two of the vaccination was, frankly, absurd and biologically impossible. His opinion that M.W. experienced autoimmune encephalitis was highly speculative, unsupported, and completely unpersuasive. In a matchup concerning whether vaccines can or do actually cause ASD, Dr. Wiznitzer is far more qualified to opine and is more persuasive than Dr. Shafrir. Doctor Wiznitzer's better qualifications and Dr. Shafrir's poor courtroom demeanor[8] have little bearing on the largely factual and legal issues presented in this case.

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with light switches," which are seen in most toddlers, but those with ASD take it to excess. Tr. at 329. He described those with ASD as having "areas of major fascination, numbers, letters, signs, certain subjects," "resistance to change in routine," and very rigid behaviors. Tr. at 329. They are often hypersensitive or hyposensitive to stimuli, meaning that they are "bothered by visual or auditory or tactile" stimuli much more than the average child. Tr. at 330. They may appear insensitive to pain. Tr. 330. Symptoms of ASD generally manifest in the second year of life, usually manifesting between 18-24 months of age. Although subtle features of ASD may be present earlier, they become more obvious when social demands rise. Tr. at 330-31.

[7] "The Committee recognizes that there is public debate over the incidence of illnesses that coincidentally occur within a short time of vaccination. The Committee further recognizes that the deeming of a vaccine-relatedness adopted here may provide compensation to some children whose illness is not, in fact, vaccine-related."

[8] Doctor Shafrir presents challenges in a courtroom setting. Repeatedly, both when sitting at counsel table and when on the witness stand, Dr. Shafrir muttered, sometimes apparently to himself and sometimes in answer to questions. He interrupted questions, attempting to answer before the question was fully framed, and tried to answer the question he wanted asked, rather than the ones counsel and I were asking. I had to ask him repeatedly to speak up or repeat himself. At times, he used the witness stand as a bully pulpit, railing against the autism establishment, and the mainstream approach to

After considering the record as a whole, I hold that petitioners are entitled to compensation for M.W.'s condition.

## I. Procedural History.

Shortly after they filed their petition, petitioners filed medical records, affidavits, and a report from a neurologist, Dr. Arnold P. Gold. Petitioners' Exhibit ["Pet. Ex."] 24.[9] They filed their statement of completion on August 9, 2012. Respondent's Vaccine Rule 4(c) report, filed on December 18, 2012, recommended against compensation.

At a status conference on February 6, 2013, the special master previously assigned to this case observed that the symptoms described in the records did not appear to meet the Table definition of an acute encephalopathy. Petitioners requested a fact hearing to elicit the parents' testimony concerning M.W.'s health in the days and months following the July 6, 2009 vaccination. Order, issued Feb. 8, 2013. The hearing was subsequently scheduled for May 15, 2013. Order, issued Mar. 13, 2013, at 1.

The case was reassigned to me on April 2, 2013. I conducted a telephonic status conference on April 10, 2013 to discuss the arrangements for the fact hearing, which was to remain as previously scheduled. I ordered petitioners to file affidavits from two additional witnesses prior to the fact hearing. Order, issued Apr. 10, 2013. On March 24, 2013, petitioners filed affidavits from Donna Sierra and Mary Valentine. Pet. Exs. 88 and 89, respectively.[10]

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diagnosis and treatment of ASD. He claimed that ASD was not genetic in nature, because there was no such thing as a "genetic epidemic." His hyperboles were not helpful in explaining the basis for his opinions and made them appear less than reliable. For example, at one point Dr. Shafrir claimed that the increase in ASD prevalence was akin to epidemics such as polio, the plague, and the Black Death (all of which he agreed were communicable diseases, unlike ASD). Tr. at 259, 417, 425-26. While I did not reject Dr. Shafrir's opinions based on his fervor and hyperbole, both detracted from his presentation. In this case, he did a poor job of advancing his belief that some forms of autistic regression are, in fact, a form of autoimmune encephalitis — one that he recently presented in a somewhat more coherent and focused fashion, albeit unsuccessfully (*see Lehner v. Sec'y, HHS,* No. 08-554V, 2015 WL 5443461 (Fed. Cl. Spec. Mstr. July 22, 2015))

[9] In this decision, citations to medical records, laboratory reports, and similar documents are made using a "Pet. Ex. #, p. #" format. Citations to other petitioners' exhibits, such as affidavits, expert reports, and medical literature use a "Pet. Ex. # at __" format. Transcript pages also use an "at" format. Respondent's exhibits are cited using "Res. Ex. at __." format.

[10] Petitioners did not assign exhibit numbers to these affidavits when they were filed. *See* ECF No. 33. In a May 1, 2013 non-pdf order, I designated them as Pet. Exs. 27 (affidavit of Donna Sierra) and 28 (affidavit of Mary Valentine). However, petitioners later assigned these exhibit numbers to other documents. *See* Pet. Ex. List, filed June 30, 2014. Therein they acknowledged the duplication, but did not assign these affidavits new exhibit numbers. Therefore, Ms. Sierra's affidavit is redesignated as Pet. Ex. 88, and Ms. Valentine's affidavit is redesignated as Pet. Ex. 89.

After receipt of the additional affidavits and telephone records produced in response to the subpoena, I held a telephonic status conference on May 6, 2013. During the status conference, petitioners indicated their intention to proceed solely on an off-table causation theory. I therefore cancelled the hearing and ordered the filing of expert reports.[11] Order, issued May 6, 2013.

Over the next seven months, the parties each filed expert reports. Respondent also filed medical literature and a supplemental Rule 4(c) report. I conducted a Vaccine Rule 5 status conference on November 21, 2013. Based on the matters discussed, I ordered the parties to propose dates for a two-day entitlement hearing. Order, filed Nov. 22, 2013. Between the Rule 5 status conference and the hearing, petitioners filed updated medical records, medical literature, photographs and two supplemental expert reports from their expert, Dr. Yuval Shafrir. Respondent also filed a supplemental expert report from her expert, Dr. Max Wiznitzer. Because Dr. Shafrir's second supplemental expert report was filed so close to the hearing date, I ordered that respondent would be permitted to make any response to it via testimony at the hearing. Based on Dr. Shafrir's expert report, the issue of whether M.W. sustained a Table encephalopathy was raised anew, and I permitted petitioners to proceed on both Table injury and causation in fact claims at the hearing.

The two-day hearing was held in Newark, N.J. on July 15-16, 2014. During the hearing I ordered petitioners to file the package insert for the Sanofi Pasteur Pentacel vaccine discussed during the hearing. This document was filed on August 15, 2014, and was designated as Pet. Ex. 73.

On July 22, 2014, I issued a post-hearing order permitting the parties to file additional medical literature to support the expert testimony. Order, issued Jul. 22, 2014. I stipulated that such literature be highlighted or otherwise reflect relevant provisions, and that it be filed by August 21, 2014. I also ordered the parties "to file additional medical journal articles or other authoritative literature supportive of each party's position on the timing requisite for an antibody response from the challenge of a vaccination" with regard to M.W.'s fourth dose of DTaP vaccine. I specified that this literature should address whether an antibody response could occur within 24 hours of the vaccination. *Id.*

Petitioners exceeded the limitations I placed on post-hearing evidence. On August 21, they filed an expert report and curriculum vitae ["CV"] from a specialist in allergies and immunology, Dr. Jay M. Kashkin (Pet. Exs. 75-78), and additional medical literature.[12] On August 21, 2014, respondent complied with my order to file additional

[11] Although petitioners filed two reports from a treating physician, Dr. Gold (*see* Pet. Exs. 24 and 30), they were more in the nature of medical records than an expert report. They are discussed in more detail, *infra.*

[12] They also filed an affidavit from Ms. Kathleen McAllister (Pet. Ex. 74), but I had authorized them to do so during the hearing. *See* Tr. at 5-6. Although I indicated that respondent could propound interrogatories to Ms. McAllister (Tr. at 6), respondent's counsel never requested to do so.

medical literature, filing Res. Exs. D-J. Petitioners filed more medical literature on September 2, 2014, again without leave of court to do so. Pet. Exs. 79-87.

Although post-hearing briefs on specific issues were discussed at the hearing (*see* Transcript ["Tr."] at 433-35) and in my initial post-hearing order, I did not order briefs to be filed, based on the matters submitted post-hearing and my review of the transcripts. Neither party specifically requested the opportunity to file post-hearing briefs.

With the last filing of medical literature on September 2, 2014, this matter became ripe for resolution. I regret that my decision to award compensation has taken more than a year to issue but, as indicated above, the issue of whether M.W. sustained a Table injury was an extremely close call. The Federal Circuit's guidance on how to resolve cases where the evidence is in equipoise remains somewhat muddled. *See, e.g.*, *Althen v. Sec'y, HHS*, 418 F.3d 1274, 1280 (Fed. Cir. 2005) (close calls should be resolved in favor of petitioner); *but see Knudsen v. Sec'y, HHS*, 35 F.3d 543, 550 (Fed. Cir. 1994) (when evidence is in equipoise, the party with the burden of proof fails to meet that burden). Although the evidence here is close, it is not in equipoise, and I find in favor of petitioner.

## II. Requirements for a Table Encephalopathy.

To prove a Table injury, petitioners must show that "the first symptom or manifestation of the onset…of any such illness, disability, injury, or condition…occurred within the time period after vaccine administration set forth in the Vaccine Injury Table." *Shalala v. Whitecotton,* 514 U.S. 268, 270 (1995) (quoting 42 U.S.C. §11(c)(1)(C)(i)). In such cases, causation is presumed. *See* 42 C.F.R. § 100.3. To establish a Table encephalopathy, petitioners must demonstrate that M.W. suffered an "encephalopathy" as defined by the QAI section of the Vaccine Injury Table within seventy two hours of his DTaP vaccination.

1. The Table Definitions.

According to the QAI, a vaccinee is considered to have suffered a Table encephalopathy if he or she manifests an injury encompassed in the definition of an acute encephalopathy within the appropriate time period, and if a chronic encephalopathy is present for more than six months after the immunization. 42 C.F.R. § 100.3(b)(2).

An acute encephalopathy is "one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred)." 42 C.F.R. § 100.3(b)(2)(i). It must persist for at least twenty-four hours and must meet at least two of the following criteria: (1) a significant change in mental status, specifically a state of confusion, delirium, or psychosis, that is not medication related; (2) a significantly decreased level of consciousness, which is independent of a seizure and cannot be attributed to the

effects of medication; and (3) a seizure associated with loss of consciousness. 42 C.F.R. § 100.3(b)(2)(i)(B).

A significantly decreased level of consciousness is indicated by the presence of one of three clinical signs for a period of at least 24 hours: "(1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli); (2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or (3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things)." 42 C.F.R. § 100.3(b)(2)(i)(D). "Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle are insufficient, standing alone or in combination, to demonstrate an acute encephalopathy." 42 C.F.R. § 100.3(b)(2)(E).

A chronic encephalopathy is defined in the QAI as "a change in mental or neurologic status, first manifested during the applicable time period [that] persists for a period of at least 6 months from the date of vaccination." 42 C.F.R. § 100.3(b)(2)(ii). If a person returns to a typical neurologic state after suffering an acute encephalopathy, he or she is not presumed to have suffered residual neurologic damage and "any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy." *Id.*

2. Interpretation of the Table Provisions.

"The symptoms associated with an acute encephalopathy are neither subtle nor insidious." *Waddell v. Sec'y, HHS*, No. 10-316, 2012 WL 4829291, at *6 (Fed. Cl. Spec. Mstr. Sept. 19, 2012). As noted in *Waddell*, "[t]he hospitalization requirement underscores how serious the symptom presentation must be after vaccination to merit classification as a Table encephalopathy." *Id.* at *7 (citing to Revision of the Vaccine Injury Table, 60 Fed. Reg. 7,685, 7,687 (Feb. 20, 1997) (preamble to final rule) ("[W]e did not intend that hospitalization be viewed as an absolute requirement to establish an acute encephalopathy, but rather as an indicator of the severity of the acute event.").

In contrast, encephalopathy,[13] as commonly used in the medical community, encompasses a much broader class of injuries than the more stringent definition of acute encephalopathy found in the QAI. As explained in *Waddell*, "[t]he scope of the medical term 'encephalopathy' is more expansive than the narrower, statutory definition set forth in the Table." *Id.* at *12 (referencing *Hazlehurst v. Sec'y, HHS*, No. 03-654V, 2009 WL 332306, at *26-29 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd,* 88 Fed. Cl. 473 (2009), *aff'd,* 604 F.3d 1343 (Fed. Cir. 2010)). The QAI definition of acute encephalopathy simply does not encompass every type of brain dysfunction to which the broader meaning of "encephalopathy" applies.

[13] Encephalopathy is defined as "any degenerative disease of the brain." DORLAND'S at 614. There are a number of specific types of encephalopathy, with a variety of causes ranging from infections such as HIV to mitochondrial disorders with neurologic manifestations. *Id*. at 614-15.

As noted in *Waddell* by then Chief Special Master Campbell-Smith,[14] the QAI definition of significantly decreased level of consciousness implies "a state of diminished alertness that is much more than mere sleepiness or inattentiveness . . . [it] requires markedly impaired - or strikingly absent - responsiveness to environmental or external stimuli for a sustained period of at least twenty-four hours." *Waddell*, 2012 WL 4829291, at *7.

The revised QAI definition aimed to differentiate between the "diminished alertness and motor activity [] which characterize [a] lethargic infant or child" and the "more serious impairment of consciousness that is the hallmark of encephalopathy (i.e., obtundation, stupor and coma)."[15] Revision of the Vaccine Injury Table, 60 Fed. Reg. at 7687; *see also Romano v. Sec'y, HHS*, No. 90-1423, 1993 WL 472879, at *6 (Fed. Cl. Spec. Mstr. Nov. 1, 1993) (citing Gerald Fenichel, CLINICAL PEDIATRIC NEUROLOGY (1st ed. 1988) at 42) (explaining that among the altered states of consciousness associated with an encephalopathy are states of: (1) increased consciousness, which can present as delirium; and (2) decreased consciousness, which can present as lethargy, obtundation, stupor, or coma.). Dramatic or severe symptoms must be present to meet the Table encephalopathy definition.[16]

## III. Evidence and Factual Findings.

The only real factual dispute in this case is what happened immediately before and after M.W.'s July 6, 2009 vaccination. I therefore set forth his uncontested medical history in a summarized fashion, followed by the matters in conflict.

[14] On September 19, 2013, Chief Special Master Campbell-Smith was appointed Judge of the U.S. Court of Federal Claims. On October 21, 2013, Judge Campbell-Smith was designated as the Chief Judge of the U.S. Court of Federal Claims.

[15] Obtundation is "mental blunting with mild to moderate reduction in alertness." Dorland's at 1310. "Stupor" is defined as "a lowered level of consciousness manifested by the subject's responding only to vigorous stimulation." *Id*. at 1789

[16] *See*, *e.g., Jay v. Sec'y, HHS*, 998 F.2d 979, 981, 984 (Fed. Cir. 1993) (noting the Special Master's comment that "[w]ith an encephalopathy we have typically seen at least one dramatic aspect. This aspect is what separates the events from the normal range of DTP reactions" and concluding that the "dramatic aspect" in the case was the child's death); *Gamache v. Sec'y, HHS,* 27 Fed. Cl. 639, 642 (1993) (upholding a dismissal decision in which the special master had concluded that "screaming and crying in and of themselves are not conclusive evidence of encephalopathy. [The vaccinee's] high-pitched and unusual screaming and inconsolable crying are explainable as a local, systemic reaction to the DPT vaccine rather than as indicia of encephalopathy."); *Watt v. Sec'y, HHS*, No. 99-25V, 2001 WL 166636, at *8 (Fed. Cl. Spec. Mstr. Jan. 26, 2001) (citing expert testimony that the symptoms relied upon to establish a Table encephalopathy "cannot merely be crying, it cannot--inconsolable crying; it cannot merely be crankiness; it cannot merely be a number of things.").

A. Health and Development through 19 Months of Age.

M.W. was born in early December 2007, after an uneventful pregnancy. Pet. Exs. 1; 4, p. 289; Tr. at 9. He appeared to develop normally. Pet. Ex. 4, pp. 279-80, 282-83. He passed a developmental screening test administered at his nine month well-child visit; he crawled, pulled to stand, and said "mama" and "dada." *Id.*, p. 274.

A switch in pediatricians to Valley Pediatric Associates ["Valley Pediatrics"] occurred around the time of his first birthday. At M.W.'s one year well-child visit, his first visit to Valley Pediatrics, he walked, babbled, and had good receptive language.[17] Pet. Ex. 5, p. 325; *see also* Pet. Exs. 6 and 7 (parent affidavits indicating that M.W. was meeting developmental milestones at one year of age: walking, talking a bit, and feeding himself). At his 15 month well-child visit, he was mildly ill, and was reported to say "mommy," "daddy," "Lily" (the name of M.W.'s older sister) and two other undecipherable words.[18] Pet. Ex. 5, p. 332.

The only thing at all unusual regarding M.W.'s well-child appointments was his parents' attitude toward the routine childhood immunizations. Although the vaccine schedule calls for the initial hepatitis B vaccination to be administered shortly after birth, his parents declined it then and again at his two week well-child visit.[19] Pet. Ex. 4, pp. 282, 301. The record from this visit indicated that vaccines were discussed, but the content of the discussion was not reflected.[20] *Id.*, p. 282. M.W. missed his one month well-child visit, but at a visit two weeks later, the file reflected that M.W. would start receiving his vaccines at two months of age, and that the revised schedule would require an additional dose of the hepatitis B vaccine. *Id*., p. 283.

A very short note reflecting concern about immunizations appears on the record for M.W.'s two month well-child visit, but he received his initial vaccinations (Pediarix, Hib, Prevnar, and Rotateq) at this February 11, 2008 visit. Pet. Ex. 4, pp. 267, 284. No reports of ill effects appear in the medical records as a result of these vaccinations, but Mrs. Wright's December 2009 narrative of M.W.'s medical history reflected that he had

[17] Unlike many pediatric practices, Valley Pediatrics did not use different preprinted forms for well-child and sick-child visits. However, the well-child visits can be discerned by the check marks on the "Education" section of the form.

[18] The handwriting on many of the Valley Pediatrics records was unusually poor. *See generally* Pet. Ex. 5.

[19] The childhood vaccination schedule recommended by the Centers for Disease Control and Prevention ["CDC"] may be found at the following: http://www.cdc.gov/vaccines/schedules/easy-to-read/child.html (last visited Sept. 9, 2015).

[20] Mrs. Wright testified that she initially refused the hepatitis B vaccination because it could be administered as part of another vaccine and would thus subject M.W. to fewer shots. Tr. at 96-97. M.W. received the Pediarix vaccine at 10 weeks, four months, and six months of age. *See* Pet. Ex. 4, p. 267. Pediarix is the trade name for a combined diphtheria, pertussis, and tetanus ["DTaP"], hepatitis B, and inactivated polio ["IPV"] vaccination. PHYSICIANS' DESK REFERENCE ["PDR"] at 1285 (66th ed. 2012). at 1285 Thus, M.W. received in one injection what would otherwise have been three separate injections.

a fever after these vaccinations and received Tylenol.[21] Pet. Ex. 25, p. 850. He received the same types of vaccinations at his four month well-child visit. Pet. Ex. 4, p. 280. Again, Mrs. Wright reported in her December 2009 narrative that he had a fever that responded to Tylenol after these vaccinations, but no other "major reactions." Pet. Ex. 25, p. 851. He had the same vaccinations at his six month well-child visit. Pet. Ex. 4, p. 279. There was no report of any reaction to these vaccinations. At nine months of age, Mrs. Wright refused the recommended influenza vaccine for M.W.[22] *Id.*, p. 274.

At M.W.'s first visit to Valley Pediatrics, the influenza vaccine was discussed, but not administered. Pet. Ex. 5, p. 325. He received Prevnar and a varicella vaccination at this December 15, 2008 visit. *Id.* At his 15 month well-child visit, for reasons not stated in the record, his measles, mumps, and rubella ["MMR"] vaccination was postponed.[23] It does not appear that this vaccination was ever administered. *See id*., p. 324 (vaccination record). Mrs. Wright had no clear explanation for why M.W. did not receive this vaccination. She testified that she thought it was being given when a child was two years of age. Tr. at 98. She later told Dr. Neubrander that she was "not going to give [M.W.] another shot after the experience he had in July after that Pentacel shot." Pet. Ex. 25, p. 832. However, that did not explain why the MMR was not given in April 2009 as planned, which even Dr. Shafrir thought was very surprising. Pet. Ex. 27 at 970.

Between January 2008 and July 2009, petitioners took M.W. to see his pediatricians for several childhood illnesses. M.W. had a gastrointestinal and respiratory illness, accompanied by thrush, when he was a little over a month old. Pet. Ex. 4, p. 294. The illnesses resolved but the thrush returned about two weeks later and was treated with Nystatin, an antifungal medication. *Id.*, p. 283. In February 2008, M.W. saw his pediatrician on three successive days for symptoms of an upper respiratory infection. *Id*., pp. 291-93. He was not seen again for illnesses until he was a little over a year old, when he had pneumonia and an ear infection. He was seen on four occasions for this illness, twice before Christmas Day and twice afterwards. Pet. Ex. 5., pp. 326-30. At the last visit, his fever was decreased and his pneumonia had resolved. *Id.*, p. 330. He was seen once more in follow-up for this illness, on January 5,

[21] This narrative, entitled "[M.W.]'s Story" [hereinafter "narrative"], was prepared by Mrs. Wright in December 2009 for Dr. Neubrander, a DAN! physician. *See* Pet. Ex. 25, pp. 849-54. Defeat Autism Now ["DAN!"] physicians subscribe to treatment protocols developed by the Autism Research Institute. These treatments may include chelation and other therapies not vetted as efficacious by controlled clinical studies. *Dwyer v. Sec'y, HHS*, No. 03-1202V, 2010 WL 892250, at *20, *178 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

[22] She testified that she refused this vaccination because she had an uncle who had reacted badly to the influenza vaccine and her husband had felt "lousy" after receiving one. She added that even though she used to receive influenza vaccines routinely, she "still got sick and still got the flu." Tr. at 97. She added that she did not have a lot of faith in the efficacy of the influenza vaccine. *Id*.

[23] An entry on this form accompanying the notation about postponing the MMR vaccination appears to be either "H/B" or "Hib," but his vaccination record does not reflect any Hib vaccine being administered on this date, March 12, 2009. Pet. Ex. 5, pp. 324, 332. "H/B" could refer to "husband," in which case the first part of the "Plan" section of the form would read "[husband] will not "r" MMR until 4/09." *Id.*, p. 332.

2009; both the pneumonia and ear infection were resolved, although he remained on antibiotics. *Id.*, p. 331. M.W. had a mild upper respiratory infection at the time of his 15 month well-child visit in March 2009, and another upper respiratory infection in May 2009. *Id.*, pp. 332-33. He did not have another physician's visit until July 2009, at which the allegedly causal vaccinations were administered.

B. Events Surrounding M.W.'s 19 Month Vaccinations.

1. The Vaccination.

M.W., then 19 months old, was seen for his 18 month well-child appointment on July 6, 2009.[24] Pet. Ex. 5, pp. 324, 339. Mrs. Wright testified that she had driven back from her mother's home in upstate New York the evening prior to M.W.'s Monday morning well-child visit. Tr. at 14. They got up early and Mr. Wright took M.W.'s older sister to the babysitter (Mrs. Donna Sierra) while she drove M.W. to his appointment,[25] which was scheduled for 8:45 AM. She and M.W. arrived early, so they walked around in the very hot weather, trying to kill time. Tr. at 13-15; *see also* Pet. Ex. 6, ¶ 16.

While waiting to see the doctor, M.W. had a snack and a drink. He became impatient and upset at the long wait and vomited and became more upset and agitated after vomiting. Tr. at 14-18, 68; Pet. Ex. 6, ¶16. Mrs. Wright informed the pediatrician, Dr. Leifer, that M.W. had vomited in the waiting room and asked if he should still be vaccinated. Doctor Leifer examined M.W., questioned Mrs. Wright about how he was feeling, and Mrs. Wright said he was fine. According to Mrs. Wright, Dr. Leifer found M.W. "to be a happy, playful and a well-child"[26] and the Pentacel vaccine was administered by a nurse at about 9:30 AM. Tr. at 16-17, 19; Pet. Ex. 6, ¶ 16; Pet. Ex. 5, p. 334.

Mrs. Wright's narrative, prepared in December 2009 for Dr. Neubrander, differed only slightly from her affidavit. She wrote that M.W. projectile-vomited going into the doctor's office (Pet. Ex. 25, p. 852), rather than while in the reception area as stated in her affidavit. The other point where the affidavit and the narrative differ was that the narrative reflected that M.W. was hysterically crying while being examined, and

[24] Unlike the other well-child visits at Valley Pediatrics, the "Education" section of the form contains no check marks, but the fact that this was a well-child visit was not contested and the "Assessment" section of the form reflected that M.W. was a well 19 month old. Pet. Ex. 5, p. 334.

[25] This conflicts with Ms. Sierra's affidavit, which stated that M.W. had been at her home on July 6, 2009, prior to his vaccination and that he had vomited while at her home. Pet. Ex. 88, ¶ 4. However, she testified that she was mistaken in her affidavit, explaining that she did not care for M.W. until later in the week after his vaccination. Tr. at 208, 218.

[26] The top portion of the medical records for this visit reflected the "happy/playful" comment Mrs. Wright referenced, and likely referred to M.W.'s presentation before he vomited. Pet. Ex. 5, p. 334. The two words which follow this remark are not decipherable. *Id*. The next line appears to read "Drank/ate" but the next two-three words are also indecipherable. *Id*. The last two lines read "Vomited post crying in waiting room." *Id*.

indicated that the physician urged her to have M.W. vaccinated so that he would not have to be put through the same scenario again. *Id.*, p. 853. Mrs. Wright testified that M.W. was quite upset when the nurse came into the room to administer the vaccination. Tr. at 19.

The physical examination section, which is usually completed by the physician performing the examination, does not reflect anything abnormal; the assessment section reflected "Well 19 mo old" and "Crying 2° [secondary] to" what appears to be "evaluation." The next section simply contains the word "Pentacel." Pet. Ex. 5, p. 334

Mrs. Wright testified that immediately after the administration of the vaccine, "I held him [in my lap] and he was crashed; he was out." Tr. at 19. She elaborated that after the shot "I grabbed him, and he just kind of collapsed into me, like someone who's just, you know, shagged out and tired and done." Tr. at 71. Her narrative reflected that after the vaccination, M.W. was listless, which Mrs. Wright attributed to being tired out "from throwing a fit." Pet. Ex. 25, p. 853. This account differs slightly (but not materially) from Mrs. Wright's 2012 affidavit. She asserted that M.W. "appeared spacey" after the vaccination and then "fell asleep," which did not concern her because it was near his naptime. Pet. Ex. 6 at ¶ 20.

Mr. Wright testified that M.W. had not been sick the prior weekend and had appeared to be having a great time. He did not appear to be sick the morning of the vaccination either. Tr. at 117.

Based on this evidence, I conclude that M.W. ate and drank while in the waiting room, vomited in the waiting room, became agitated and upset, and was still more agitated while being examined. The pediatrician, Dr. Leifer, examined M.W. and did not record anything to suggest that he was acutely ill or too ill to receive a vaccination. M.W. received the Pentacel vaccination the morning of July 6, 2009, and most likely did so around the time (9:30 AM) reported by Mrs. Wright.

2. Post-Vaccination Drive Home.

The issue in controversy regarding what happened during the drive home from Valley Pediatrics concerns what Mrs. Wright was describing when she used the term "convulsed."

I begin with the very abbreviated description in M.W.'s records. A continuation page for the pediatric records of the July 6, 2009 visit reflects: "Mother called. Pt [patient] vomited on way home." Pet. Ex. 5, p. 335. The next word is difficult to read, but might be "Discussed." *Id.* The next entry reads "ø resp distress," which I interpret to mean "No respiratory distress." *Id.* The last line above the signature (which appears to be the same as the signature of the physician who performed the well-child examination) is "will observe [and] call when gets home." *Id.*

Mrs. Wright's narrative, affidavit, and testimony are more detailed. The narrative reported:

> In the car on the way home he convulsed but had nothing left to throw up. I now realize he most likely had a seizure. I pulled the car over and called the Dr's office because he was just kind of staring into space. They asked me a bunch of questions but thought I didn't need to come back or go to the ER and I should just give him some Tylenol/Motrin when I got home.

Pet. Ex. 25, p. 853.

This account differs slightly (but not materially) from Mrs. Wright's 2012 affidavit. She reported:

> On the way home from the doctor's office [M.W.] convulsed and vomited. I immediately pulled over to the side of the road and felt his forehead. He was warm. His head rolled backwards and he was not responding to me.

Pet. Ex. 6 at ¶ 21. The report in the affidavit concerning her call to the pediatrics practice was essentially the same account she made in her narrative for Dr. Neubrander, but she added, "I was assured that he would be fine." *Id.*; *see also* Tr. at 27.

Mrs. Wright testified that, as she drove M.W. home around 10:00 a.m., she noticed that he was failing to interact with her. Tr. at 20. When she looked back at him, his head was back and to the side, his eyes were rolled back, and he "convulsed," which she described as shaking. She could not recall if he stiffened as well. Tr. at 73. She called his name and he did not respond ("seemed out of it"). Tr. at 20-21, 73. She pulled the car to the side of the road, and went over to his side of the car, by which time he had stopped convulsing. Tr. at 73-74. He vomited after he stopped shaking, and the shaking did not last very long. Tr. at 21-22, 73. She described him as "spacey" and "out of it." Tr. at 21. M.W. did not look at her. Mrs. Wright said he was "just out of it and zoned out." Tr. at 21.

Using 411 services, she reached Valley Pediatrics, where she reported that M.W. had "just convulsed" and asked to speak to the doctor. Tr. at 21-22. Doctor Leifer came on the telephone quickly, and asked Mrs. Wright to describe what had happened. Mrs. Wright asked if she should take M.W. to the emergency room or back to the practice. The doctor told her to take him home and monitor him, and that someone from the practice would call. Tr. at 22. Mrs. Wright testified that her cell phone records showed that the call occurred at about 10:08 or 10:10. Tr. at 72. This would have been about 15-20 minutes after leaving the practice. Tr. at 72-73.

In his testimony and affidavit, Mr. Wright also recounted what he was told about the events in the car. His affidavit reflected that his wife called him on her way home

and reported that "[M.W.] convulsed and vomited in the car. She stated that M.W. was running a fever and she believed he had a seizure of some sort" and that she had called the doctor's office and was told he would be fine and that this was normal after vaccinations. Pet. Ex. 7, ¶ 10. I note that at no point in her testimony did she claim that M.W. had a fever in the car, although consistent with her affidavit, Pet. Ex. 6 at ¶ 21, she said he felt "warm." Tr. at 29, 75. She also testified that it was 90° that day and she didn't know if M.W. was running a fever or not. Tr. at 75.

Mr. Wright testified similarly, but did not mention the fever in the car. He described Mrs. Wright as "quite unconsolable" and that she was "really scared or really upset." Tr. at 115. He mentioned fever in the context of the advice from the pediatric practice to monitor M.W.'s temperature because "he was apparently getting a fever." Tr. at 115.

Ms. Sierra testified that Mrs. Wright called her the afternoon of July 6, 2009, to tell her that she would not bring M.W. over for babysitting; instead, because of the convulsions in the car, she was taking him home. Tr. at 208-09.

M.W.'s great aunt, Mary Valentine,[27] signed an affidavit in April 2013, which reflected that her niece had called her the day of the vaccinations and reported that M.W. threw up in the doctor's office and recounted Mrs. Wright's telephone conversation with the pediatric practice. Pet. Ex. 89 at ¶ 7. Ms. Valentine also indicated that Mrs. Wright asked if she should take M.W. to the emergency room. *Id.* At the hearing, she acknowledged that there was no telephone call to or from her and the petitioners that day, but rather that the call occurred on July 10. Tr. 180-81, 193.

Ms. Valentine testified that when she spoke with Mrs. Wright on July 10, 2009, Mrs. Wright informed her that M.W. had thrown up, had convulsed in the car, that M.W. was just lying around, and that she had called the pediatrician's office several times. Tr. at 181-82. Ms. Valentine testified that she shared her story of her daughter's lethargic reaction after a vaccine with Mrs. Wright, as she was "trying to make her feel better." Tr. at 182.

One of the post-hearing filings by petitioners was an affidavit from another of Mrs. Wright's aunts, Ms. Kathleen McAllister. *See* Pet. Ex. 74. During the hearing, Mrs. Wright testified that some of the telephone calls listed on Pet. Ex. 26 placed on July 6-7, and 9-10, 2009, were calls to or from "Aunt Kathy." She explained that the calls she thought were made to Ms. Valentine were actually to her other aunt, Kathy McAllister. Tr. at 38-42. Ms. McAllister's affidavit confirmed that these calls were made and that they discussed M.W.'s condition after his vaccination on July 6. Pet. Ex. 74. Ms. McAllister did not profess an exact memory of what was said, but she did remember

[27] Ms. Valentine is a teacher with over 28 years of experience, and has taught special education students. Tr. at 177. She indicated that she was teaching first grade at the time of the hearing. *Id.*

Mrs. Wright reporting that M.W. convulsed in the car on the way home from the doctor's office and asked the doctor if she should take him to the emergency room. *Id*. at ¶¶ 6-7.

Doctor Shafrir did not really address what he thought had transpired in the car, other than to say that he thought M.W. experienced an acute encephalopathy. Tr. at 288. He thought, based on Mrs. Wright's descriptions, that M.W. lost consciousness during the seizure. Tr. at 234, 292.

Doctor Wiznitzer testified that, based on Mrs. Wright's descriptions of the events in the car, he could not determine what she meant by "convulsion," because she simply said that M.W. shook. Tr. at 347. Rather than an epileptic event or a seizure, he referred to the event as a paroxysmal[28] event, and added "if you want to use the generic term 'seizure' to apply to things that may be epileptic or non-epileptic; in other words, arising from the brain or not, then you can use that term." Tr. at 347. He added that there are many reasons why children have paroxysmal events. Tr. at 347, 392. He explained that the shaking she described could simply have been associated with the subsequent vomiting. Tr. at 348. He indicated that vomiting was not a common event after experiencing a seizure, although it could happen. Tr. at 391.

I find that the events in the car occurred within two hours of M.W.'s initial vomiting episode, and within one hour of his vaccination. I base these time frames on Mrs. Wright's testimony about the time of the appointment (8:45 AM), on some time being spent in the waiting room, on the vaccines being administered after M.W. was examined by Dr. Leifer, on Mrs. Wright's being 15 to 20 minutes into the drive home when M.W. convulsed and vomited, and on her making the telephone call to the pediatric practice at around 10:08 to 10:10 AM.

Based on the evidence available, I find that M.W. most likely experienced a brief seizure in the car on July 6, 2009. The description of his head thrown back and turned to the side, eyes rolled back, and convulsive shaking are consistent with a seizure. His lack of responsiveness to his name and his mother's presence are consistent with a loss of consciousness, and thus I find that the seizure was one accompanied by a loss of consciousness. Mrs. Wright's descriptions of M.W.'s behavior and symptoms after the vaccination strongly suggest a post-ictal state.

I find it unlikely that she used the term "seizure" to anyone on the day of the vaccination. Had she reported that M.W. had a seizure to anyone at the pediatrics practice, most pediatricians would have reflected that in the record.[29] Mrs. Wright was

[28] "Paroxysmal" is defined as a sudden intensification of symptoms, a spasm, or a seizure." DORLAND'S at 1384. Thus, even Dr. Wiznitzer's testimony is consistent with M.W. experiencing a seizure.

[29] Doctor Shafrir was highly critical of Valley Pediatrics' record keeping, particularly regarding the lack of documentation of the many telephone calls between the Wright residence and the practice. *See* Pet. Ex. 27 at 983. Doctor Wiznitzer conceded that the record keeping was poor and that conversations with the doctor or nurse at Valley Pediatrics should have been documented. Tr. at 411-12.

clearly distressed by what she witnessed, and whatever she told the person who answered the telephone at the pediatric practice sounded urgent enough to interrupt Dr. Leifer and get her on the telephone. However, Dr. Leifer's questioning of Mrs. Wright about what had happened either did not elicit answers that would reflect that M.W. had suffered a seizure or, alternatively, Dr. Leifer may simply have doubted her account. That does not change the description provided in Mrs. Wright's relatively consistent affidavit, statement to Dr. Neubrander, reports to family members and Ms. Sierra, reports to other physicians and, most importantly, her testimony at the hearing.[30]

3. M.W.'s Medical Condition During the Week after Returning Home.

M.W. did not see a physician between his 19 month well-child visit and his first visit to Bergen West Pediatrics in October 2009. Pet. Ex. 8, p. 364 (reflecting the October 26, 2009 visit).[31] Mr. Wright briefly visited Valley Pediatrics on July 9, 2009 to retrieve a copy of M.W.'s records,[32] but the records do not reflect any discussion of M.W.'s condition at this point. *See* Pet. Ex. 5, p. 335; Tr. at 147-48.

Thus, the only available evidence regarding M.W.'s condition after the vaccination is from his family members and caregivers. Telephone records corroborate that some of the telephone calls were made as reported.[33] With the exception of Dr. Neubrander's records, which contain Mrs. Wright's narrative, later medical records contain little detail about what M.W. experienced in the week or so after the July 6, 2009 vaccinations. *See* Pet. Exs. 5, p. 335; 9, pp. 430-34; 13, p. 605.

b. Events Specific to July 6, 2009.

As advised by Dr. Leifer, Mrs. Wright continued the drive home. When she arrived, she cleaned the vomit off M.W. and put him on the couch and then she cried

[30] In my long experience as an attorney, judge, and special master, I have rarely seen prior statements of lay witnesses at trial contain all the details that are elicited during testimony. This is not always because the details did not occur, but because earlier statements are not prepared with the benefit of clarifying questions from someone who did not observe the events described. Mrs. Wright appeared to me to be testifying forthrightly. While recall of events that occurred years earlier is always colored by outside factors, I found her testimony, affidavit, narrative, and histories provided to health care providers to be relatively consistent.

[31] There was an earlier telephone call to the NJ early intervention referral line, but no actual physician visit. Pet. Ex. 9, pp. 430-34 (records from the referral line call).

[32] Mr. Wright testified that he made two such visits, one on July 8 and one on July 9, and that he was quite irate at both visits. Tr. at 123, 168.

[33] The very fact that the pediatric practice called the Wright home so frequently in the days after the vaccination reflects, based on my years of experience as a special master, some heightened degree of concern about M.W.'s condition, and perhaps some second-guessing of the decision not to send M.W. to the emergency room or back to the office to be checked out. It is far more likely for parents to report that they contacted or tried to contact a pediatric practice than it is for the practice to make so many calls to the patient's parents.

because she was so upset by what had happened. Tr. at 23. She testified that she did not take M.W.'s temperature after she got him home from the doctor's office, but did give him Tylenol.[34] Tr. at 76. He spent the entire day on the couch so that she could watch him, except when she carried him from room to room. M.W. slept off and on the entire day. Tr. at 23-24; Pet. Ex. 6 at ¶ 22. Mrs. Wright testified that "I was tired, too, so I was laying [sic] and sleeping with him all day long, too." Tr. at 30; *see also* Tr. at 121.

Mrs. Wright testified that she did not speak to Dr. Leifer from her home telephone that day. Tr. at 26. In the call documented as occurring at 12:26, the pediatric practice called her to inquire if M.W. was okay. She testified that she told the office staff that M.W. was "spaced out" and just "laying [sic] around." Tr. at 27. According to the telephone records, this call lasted 35 seconds. Pet. Ex. 26, p. 961 (first highlighted record).

Mrs. Wright described M.W. as not talking, not responding, zoned out, and spacey for the remainder of the day. Tr. at 23-24. Although the TV was on, M.W. was not watching it. Tr. at 24. He did not play at all that day. Tr. at 30. When she stood in front of him and said his name, he would "kind of look over." Tr. at 24. M.W. did not eat, but drank a bottle. He continued to produce urine. Tr. at 30-31. She recalled that he felt warm, but did not think he had a fever. Tr. at 29. He was not fussy or irritable. Tr. at 31. In essence, she described a child who was not responsive to her during the few periods when he was awake.

According to her affidavit, Mrs. Wright called the pediatric office that day "to reconfirm that I should not return with [M.W.]." She indicated that the doctor was unavailable and that she spoke with a nurse who reassured her that the reaction was normal. Pet. Ex. 6 at ¶23. Her testimony varied slightly; she testified that she made a call to the pediatric practice at 16:19 (4:19 PM) that day. She was upset because no one from the office had called her back.[35] She spoke with receptionists who asked her questions and told her to give M.W. Tylenol, and she asked to speak to a doctor or a nurse. Tr. at 28. The telephone records reflect that this call lasted 104 seconds. Pet. Ex. 26, p. 961 (call originated at 16:19:19, not highlighted). At that point, M.W. did not have a fever, although he felt warm. Tr. at 28-29.

Although it is not clear from the transcript, it appears that Mrs. Wright then began discussing the third telephone call between her home and the pediatric practice that day. Tr. at 29. That call is reflected on the telephone records as a call from the home

[34] Tylenol administration is often recommended prior to or after a vaccination to prevent fever and alleviate the pain of the vaccination. Mrs. Wright's narrative reflected that she usually gave M.W. Tylenol after vaccinations. Doctor Leifer may have recommended administration of Tylenol during the post-vaccination telephone call based on Mrs. Wright's report that he felt warm.

[35] The telephone records reflect the call from the pediatric practice to the Wright home at 12:26 (12:26 PM), but no calls after that. Presumably, Mrs. Wright had anticipated another telephone call from the practice that had not occurred.

to the practice at 17:03:33, lasting a little less than 10 minutes. Pet. Ex. 26, p. 961 (third highlighted telephone call). Mrs. Wright indicated that she asked to talk to the nurse or doctor, and was transferred to the nurse who administered the vaccination. She asked if she should take M.W. to the ER because he "seemed out of it" and was "spacey." The nurse responded by asking if M.W. was responding to his name or if he came when called for dinner. Mrs. Wright explained that he was just on the couch and did not seem to be responding to her. Tr. at 29. The nurse then asked if he was eating or drinking, and said that as long as he was drinking and urinating he was okay. Mrs. Wright testified that M.W. was still on the couch, and had not gotten up at all to play. Tr. at 30. He was not fussy or irritable, "just out of it." Tr. at 31. He would take a drink and then "go back to the couch." *Id*. Mrs. Wright explained that M.W. was not walking; she was carrying him to and from the couch. M.W. slept with his parents that night. *Id*.

Contrary to what has transpired in most hearings in my nearly 10 years as a special master, Mrs. Wright's testimony was not provided via leading questions. This enhanced the credibility of her testimony.

Mr. Wright described M.W. not displaying any activity for the first day or two after the vaccination, "not physically or emotionally or even verbally." He said that M.W. "was pretty much there but not there." Tr. at 118. Mr. Wright testified that "M.W. was physically and mentally somewhere else." Tr. at 145. M.W. "basically stayed listless," in spite of Tylenol. Tr. at 118. He stared into space when he was awake. Tr. at 145-46.. He agreed with his wife that M.W. slept most of the day and night of July 6, 2009. Tr. at 121. He could not recall if M.W. was drinking or just "sucking on his baba," but he recalled that he was not eating. Tr. at 145. He testified that M.W. did not begin walking until late Wednesday or Thursday (July 8-9), although he may have gotten out of bed once on the second day, but that M.W. was basically immobile. Tr. at 150.

He recounted that Mrs. Wright wanted to take him to the emergency room or back to the doctor, and he kept reminding her that the doctor said he would be fine. Tr. at 121, 146-47.

c. Events Specific to July 7, 2009.

M.W. woke up during the night, and was given something to drink. Tr. at 32. According to Mrs. Wright's affidavit, M.W. slept nearly the entire day of July 7, 2009, waking up for only a few minutes. At one point, he clutched his neck and vomited. Pet. Ex. 6, ¶ 24. She indicated that she "kept calling the doctor's office and they continued to tell me to monitor him. I was very concerned because [M.W.] was not responding to me when I said his name, it seemed like he could not hear, and he had no appetite." *Id.* She called the doctor's office that afternoon, and Dr. Leifer again advised her to monitor him throughout the night.[36] *Id.*

[36] The telephone records reflect a call from the pediatric practice to the Wright home at 17:02:24, lasting 8 seconds; a similar call at 18:41:40 lasting 7 seconds, and one at 20:08:54, lasting 54 seconds. There

Her testimony was that M.W. did the same thing on July 7 that he had done the prior day—he laid around all day. Tr. at 32. He had a fever and was taking fluids and urinating. *Id.* She was annoyed at the doctor's office because the calls that day were from the receptionist, not the doctor. She testified that she talked to Dr. Leifer at the third call that day, and that the doctor asked about urinating and keeping fluids down and controlling his fever with Tylenol. *Id.*

Mr. Wright testified that M.W. "was basically catatonic for the entire day" of July 7. Tr. at 122. However, he continued to take a wait and see attitude.

Mrs. Wright testified that she made several calls on the morning of July 7 to one of her aunts, because she was upset about M.W. Tr. at 38-43. Mr. Wright testified that Mrs. Wright was upset, and particularly so after phone calls with the pediatric practice. Tr. at 119-20.

The evening of July 7, M.W. slept in his own bed on the second floor, while Mrs. Wright slept on the couch downstairs. At some point, he got up and got out of his railed bed and came to the head of the stairs and sat down. He was holding and rubbing his neck, and she went up the stairs to him. Tr. at 33. He was running a very high fever and "was just out of it." He pitched forward and vomited, but not copiously. She administered Tylenol. Tr. at 33-34. The Tylenol worked to bring down the fever, but it returned as the Tylenol wore off. Tr. at 34-35. She returned M.W. to his own bed, and slept there with him for the rest of the night. Tr. at 35.

d. The Remainder of the Week.

M.W. was better on July 8, but was still taking Tylenol and was "still out of it." Tr. at 35-36. He responded better, and was likely eating, but not a lot. He still slept a lot. Tr. at 36. There were no telephone calls on July 8th to or from M.W.'s pediatric practice. Mrs. Wright testified that M.W. was not interacting with his older sister, and was still sleeping most of the time. Tr. at 36.

Ms. Sierra saw M.W. on July 8, 2009. He recognized her by looking up at her, but his greeting was different than in prior visits. Tr. at 210. Mrs. Wright told her then that his fever was breaking. Tr. at 224. Ms. Sierra also testified that he did not look flushed to her and she assumed that he was getting better. *Id*.

The fever broke on July 9. Tr. at 37. In the two telephone calls on the 9th from the pediatric practice to the Wright home, Mrs. Wright explained that M.W.'s fever was better. However, she was unhappy with the practice, in that receptionists were giving

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were no telephone calls from the Wright's home phone to the pediatric practice on July 7, 2009. Pet. Ex. 26 at 962. It is possible that Mrs. Wright confused the telephone calls on July 6 with those on July 7.

medical advice and that she could not get the doctor to call her back and had to beg to talk with a nurse. Tr. at 37-38.

Mr. Wright visited the pediatrician's office in person and demanded to see Dr. Leifer.[37] Tr. at 123. Upon the staff's refusal, he demanded M.W.'s medical records, which he could not recall obtaining, but which are recorded as being transferred to an unidentified recipient on July 9. *Id.* at 123-24, 148, 174-75; Pet. Ex. 5, p. 335. This incident, coupled with the parents' overall frustration with Dr. Leifer's office, apparently lead him to believe that M.W. "didn't need any doctors." Tr. at 128.

According to Ms. Sierra, she spoke with Mrs. Wright about M.W.'s condition. Tr. at 209. Mrs. Wright complained that M.W. still had a slight fever and that he was still getting Tylenol, but she also reported that he was starting to "be himself" again. Tr. at 209. On Wednesday or Thursday (July 8 or 9), Mrs. Wright told Ms. Sierra that M.W. "was feeling better . . . I'll bring him around to you tomorrow. He was all right, but he was just laying [sic] around on the sofa watching TV." Tr. at 210, *see also* Tr. at 224.

Mrs. Wright and her aunt, Mary Valentine, exchanged telephone calls on July 10. Mrs. Wright explained that she was upset, having had "a rough couple of days" and that she was concerned about M.W. Tr. at 43. Ms. Valentine testified that she saw M.W. the weekend prior to his vaccination. Tr. at 180. When Ms. Valentine spoke with Mrs. Wright on July 10, Mrs. Wright told her that he had convulsed in the car and had thrown up and that she thought he was acting differently. Mrs. Wright reported that she was worried and, according to Ms. Valentine, she "sounded very, very upset." Tr. at 181-82.

On July 10, 2009, Ms. Sierra cared for M.W. She testified that he laid on the couch on his blanket with his bottle. Although he got down and crawled around a little, he was not as "perky" as he had been before the vaccination. Tr. at 210. He was less interactive with her own daughter, and Ms. Sierra described him as "spacey" or "starey-eyed." Tr. at 211-12. She indicated that he did not ask her for cookies. *Id.*

e. Findings.

I find that during the period from July 6-7, M.W. displayed a significantly decreased level of consciousness. He was not responsive to parents or his sister. He did not maintain eye contact or fix his gaze on people or objects such as the television. He did not respond to his name. He was not talking, walking, or playing. Although he drank and urinated, he did not eat. This decreased level of consciousness lasted for more than 24 hours after arriving back home on July 6, 2009. This decreased level of consciousness cannot be attributed to the only medication M.W. was taking, which was Tylenol, and was independent of M.W.'s brief prior seizure.

[37] Mr. Wright testified about two trips to Dr. Leifer's office, one on the 8th and one on the 9th of July, and on one of those days, he told the staff that he wanted to see "a real doctor." Tr. at 168.

Based on the record as a whole, including the parents' descriptions and their reports to family and Ms. Sierra, I find that M.W. was more than simply lethargic during the period from arrival at home through the next 24 hours; he was obtunded and perhaps even stuporous.

C. M.W.'s Emerging Problems Post-Vaccination.

After the July 2009 immunizations, M.W.'s babysitter and family members all described changed behaviors. The common changes in those affidavits are that M.W. no longer responded quickly to his name, spoke less, no longer slept through the night, did not want to play with others, and his eye contact grew worse. Pet. Exs. 6, pp. 343-44; 7 p. 351; 27, pp. 967-68.

For the rest of the summer, Mrs. Wright noticed M.W.'s worsening eye contact, decreased interest in play, irregular sleeping patterns, fixation with television, a heightened interest in the mechanics of toys and lettering, a need to arrange household items in a particular order, and his reaction when the order of objects was altered. Tr. at 44-45; *see* Tr. at 130-31. M.W. also failed to acknowledge his mother's calls for attention, leading her to suspect a problem with his hearing. *Id.* Similarly, Mr. Wright noticed a lack of acknowledgment from M.W. like "[h]i, Daddy," or other usual greetings like hugs. *Id.* at 126.

When Ms. Valentine visited M.W. on July 25, 2009, she recalled that, while he ordinarily would greet her and her son with a hug, he failed to acknowledge her presence or interact with her the way he did previously. Tr. at 183-84. This was a significant change, as she had seen M.W. over the weekend prior to his vaccination. For instance, M.W. failed to respond when she spoke to him. *Id.* at 186. Similarly, while he used to enjoy watching her son destroy towers of blocks, M.W. became very upset when they were knocked over, insisting that they be reconstructed in the same way they were before. *Id.* at 183. Ms. Valentine also noticed that his sleep pattern was irregular and she noticed him repeating his alphabet at nighttime. *Id.* at 184.

Ms. Valentine's affidavit stated that during her visit lasting several days at the end of July 2009, M.W. "was not talking," but during her testimony she clarified that "[M.W.] was not talking as much as he had….[but] I can't say in the six days he never spoke at all." Tr. at 196; Pet. Ex. 89 at ¶10.

Mr. Wright testified that in the days and weeks afterwards, M.W. "was in his own little world." Tr. at 126,151. He did not smile or run to his father. Tr. at 126. He described M.W. as replaying or reliving June. The things M.W. wanted to do were repetitive. He was intolerant of change. He stopped sleeping well. Tr. at 129-30. He was not speaking, not making eye contact, and responded to his name only after being called five or six times. Tr. at 130-31.

On October 21, 2009, Mrs. Wright called the New Jersey Early Intervention telephone line with concerns about M.W.'s speech, sporadic eye contact, and lack of response to his name.[38] She also expressed concern that he did "not follow directions all the time" and that he ignored his mother "a lot." Pet. Ex. 9, p. 430; *see also* Tr. at 50. The form indicated that Mrs. Wright had spoken with M.W.'s pediatrician the day prior, but that the doctor was not concerned.[39] Pet. Ex. 9, p. 432. In her testimony, Mrs. Wright confirmed the family's general concerns over M.W.'s delayed speech. Tr. at 87-89.

The new pediatrician was likely Dr. Slavin at Bergen West Pediatrics, as a record dated in October 2009 could read October 20, 2009.[40] Pet. Ex. 8, p. 364. The reason for the visit was that M.W., then 22 months old, was not making eye contact and there were concerns about his behavior, specifically about autism. The notes indicated that M.W. did not always respond to his name; sometimes lined up objects, but not excessively; pointed, imitated, showed objects to his parents; did make eye contact; did not always understand what people said; did not engage in pretend play, and spoke about 5-10 words. He was very fussy at the visit and could not be examined or weighed. Another note reflected that he failed 4 of 23 questions on the "M-CHAT screening test."[41] *Id*.; *see also* Pet. Ex. 8, pp. 361-62 (reflecting the Denver Prescreening Questionnaire, rather than the M-CHAT about which Mrs. Wright testified). The physician thought M.W. had developmental delay, possibly mild "PDD."[42] Referrals for a hearing evaluation,[43] to early intervention, and to the child development center were made. *Id*. at 364. These referrals indicated that the pediatrician did have concerns about what Mrs. Wright had reported.

A second visit to Bergen West Pediatrics practice took place on November 2, 2009, about two weeks after the contact with the Early Intervention program. The

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[38] Mrs. Wright also testified that Mr. Wright called Early Intervention as well, but did not specify when. Tr. at 86-87.

[39] What Mrs. Wright interpreted as a lack of concern on the part of M.W.'s pediatrician was certainly not reflected in the notes of the actual visit, as the assessment performed the prior day reflected that M.W. had developmental delay and possibly a mild autism spectrum disorder. *See* Pet. Ex. 8, p. 364.

[40] Mrs. Wright's testimony indicated that this pediatrician was likely Dr. Slavin. Tr. at 50.

[41] What the medical record (and Dr. Shafrir) referred to as the M-CHAT could be the Denver Prescreening Questionnaire that appears in the Bergen West Pediatrics records. Pet. Ex. 8, pp. 361-62. No copy of the M-CHAT appears in the Bergen West records. According to the Denver Prescreening Questionnaire, M.W. did not copy housework (pretend play). He could not take off clothes; point to body parts, feed himself with a spoon or fork without spilling much, or kick a small ball. *Id*., p. 361. If an M-CHAT was completed at this visit, it was not included in the records from Bergen West Pediatrics.

[42] "PDD" stands for pervasive developmental delay," and was the umbrella term in the DSM-IV-TR for what are now called autism spectrum disorders in the DSM-V.

[43] The hearing evaluation, performed on November 11, 2009, was "insufficient to make a definitive statement about [M.W.]'s hearing," but the limited data obtained suggested that he had "sufficient hearing for normal speech and language development." Pet. Ex. 11, p. 444.

record reflects that M.W. had problems with sleeping, diet, and excessive urination. M.W. used to sleep all night, but was waking up several times a night, needed his parents in the room to fall asleep while he drank a bottle, and usually napped two hours at mid-day. The previous evening, M.W. was up from 1-4 AM. He did not have excessive thirst, but was reported to drink excessive amounts of milk a day, with a limited diet of meatballs, chicken, and some fruits and vegetables. Pet. Ex. 8, p. 363. The assessment was that M.W. had sleep problems and excessive milk intake. *Id*.

D. Early Intervention and ASD Diagnosis.

On November 18, 2009, the Regional Early Intervention Team evaluated M.W. and recommended applied behavioral analysis ["ABA"][44], speech, and occupational therapies. Pet. Ex. 12, pp. 446-51; Tr. at 51. M.W. was assessed as more than 25% delayed in adaptive, social/emotional, and communication skills.[45] Pet. Ex. 12, p. 450. Mrs. Wright testified that at this point "he wasn't talking as much as he used to talk" and she suspected that M.W.'s lack of communication led to him regularly throwing tantrums out of frustration. Tr. at 51-52.

Mrs. Wright completed a parent questionnaire form for Sanzari Children's Hospital on November 24, 2009. Pet. Ex. 13, pp. 605-12. Her concerns were M.W.'s eye contact, inconsistent response to his name, lack of understanding of verbal directions, and sleep difficulties coupled with hyperactivity. She reported that these problems were first noticed in July 2009. She indicated that she was very concerned that M.W. was on the autistic spectrum. *Id.*, p. 605; *see also* Pet. Ex. 8, p. 364; Tr. at 85, 90-91. In the "Development" section of the form, she did not respond to a question about when M.W. used the terms "mama" or "dada" with meaning, and she answered the question about when M.W. responded to his name with "sometimes responds but not all the time." Pet. Ex. 13, p. 608. She reported he was "behind in speech" and that he did not use a fork or spoon, and that he had "convulsed after 18 month shots." *Id.* She described him as throwing up and listless for four days after the Pentacel vaccination. *Id.*, p. 609. In a narrative, she reported that M.W.'s "speech skills seem very behind, but he knows all his A,B,Cs and the phonics to each letter. But he doesn't say Hi or Bye unless we do it and tell him to do it. (and will only say bye then)." *Id.*, p. 612 (emphasis original).

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[44] ABA therapy consists of the "application of learning theory based on operant conditioning" and "is the only intervention recommended by the Surgeon General" for ASD. *Dwyer v. Sec'y, HHS,* No. 03-1202V, 2010 WL 892250, at 272, n.650 (Fed. Cl. Spec. Mstr. March 12, 2010) (internal citations omitted).

[45] At this evaluation, M.W. was reported to use least 10 words as labels, not counting letters. Pet. Ex. 12, p. 449. The Battelle Developmental Inventory II test, which includes a communication module, was administered (*see id*., p. 446), and M.W. scored at 5 months of age for receptive and 9 months of age for expressive language (*id.*, p. 450). The specific test components for language evaluation are at *id*., pp. 482-83 and reflected that M.W. could not attend to someone talking to him for at least 10 seconds, identify family members when named, follow three or more verbal commands, wave bye-bye, spontaneously imitate sounds, words, or gestures for objects in his immediate environment, or use 10 or more words.

As Mr. Wright reported to a physician at Bergen West Pediatrics in December 2009, M.W. was using many new words, his eye contact was improving, and he was seeking out other kids, but still not responding to his name. His diet was more varied. His sleeping problems were improving as well, and he was not taking as many naps. Pet. Ex. 8, p. 365. Mr. Wright declined an MMR vaccination at this visit, but indicated he would discuss this with Mrs. Wright. *Id*.

In an evaluation on December 21, 2009 (Pet. Ex. 15, pp. 617-22), Dr. Lisa Nalven noted that M.W.'s parents had initial concerns about his development at about 18 months of age, when Mrs. Wright observed decreased eye contact (*id*., p. 617). This coincided with his 19 month vaccination and high fever. The Wrights thought that "overall he had always made progress without loss of skills." *Id*. They described M.W. as advanced in some areas and behind in others. He used language to label, rather than to communicate, and, in labeling, had a good vocabulary. They reported he could identify letters and numbers, but appeared to overfocus on this. They also reported that he used "Daddy" for his father more than he called his mother, and did not use a word for his sister. *Id*.

The Wrights denied the accuracy of Dr. Nalven's records, specifically indicating that the histories were incorrect, and that "the first [report] we got from her was a cut-and-paste job, and it stands out that the name [of another person] was all over it, not [M.W.]." Tr. at 92-93; 162-63. Mrs. Wright denied that they had said he had always made progress without loss of skills. Tr. at 92. Mr. Wright was less definite, indicating that he had "[p]robably not" said that. Tr. at 162. However, he specifically denied saying that M.W.'s eye contact has not always been optimal. *Id*.

Doctor Nalven also recorded that Mr. and Mrs. Wright did "not report the development of early pretend play." Mrs. Wright denied that this was accurate. Tr. at 93. However, I note that the M-CHAT Mrs. Wright completed on the day of the Pentacel vaccination reflected that M.W. engaged in pretend play only sometimes. See Pet. Ex. 5, p. 338. This suggests that Dr. Nalven's notation was probably accurate. Doctor Nalven also noted that M.W. had "a tendency to toe walk," as did both of his parents, his father currently and his mother in the past. Pet. Ex. 15, p. 619. She also noted that Mr. Wright did not talk until he was three years of age. *Id.* Both of these reports were also made to other physicians. The report about toe walking was made to Dr. Neubrander (*see* Pet. Ex. 25, p. 834) and Mr. Wright's slow development of language was reflected in Dr. Gold's records from March 2010 (*see* Pet. Ex. 17, p. 636).

Doctor Nalven's impressions were that M.W. had "differences in brain development and function, which meet diagnostic criteria for an autism spectrum disorder." Pet. Ex. 15, p. 621. She described delays and qualitative differences in each of the three domains of communication, social interaction, play and behaviors. *Id.* She ordered a number of tests, and suggested re-contacting early intervention to obtain ABA services. *Id.*

Doctor Neubrander's December 31, 2009 findings were also "consistent with ASD." Pet. Ex. 25, pp. 865-67. Mrs. Wright indicated that she had sought out Dr. Neubrander because she wanted a DAN! doctor after she looked into biomedical approaches to autism treatment on the internet. She wanted a physician who would help with supplements and gut issues and anything that might make M.W. healthier and sleep better. *Id.*, p. 826. Mrs. Wright's history regarding any regression or lack of progression was that M.W. was developing normally until the Pentacel vaccination. "After that, both my babysitter and I started to notice he stopped consistently responding to his name and his eye contact was not the same as before." *Id*., p. 831.

Pursuant to Dr. Neubrander's order, M.W. was tested for MTHFR polymorphisms, and was found to have one copy of the C677T and A1298C alleles.[46] Pet Ex. 25, p. 858. Doctor Neubrander ordered methylcobalamin (B12) treatment, while acknowledging that no well-designed clinical trials had shown its efficacy. *Id.*, p. 864.

In February 2010, Mr. Wright visited Bergen West Pediatrics to talk to M.W.'s doctor about the diagnosis of autism. Mr. Wright reported that speech and ABA therapy through early intervention were helping. He also reported that M.W. had seen Dr. Neubrander, who was described as an "alternative autism doctor" and that Dr. Neubrander had recommended "B12" injections and hyperbaric oxygen therapy. The pediatrician's notes reflected a discussion "at length" about risks of alternative therapies and the lack of evidence of benefit from (and specific advice against) using a hyperbaric oxygen chamber. Pet. Ex. 8, p. 368. M.W. was assessed with mild autism, and a number of tests recommend by Dr. Neubrander were ordered. *Id.*, p. 369.

A developmental pediatric study was performed by developmental pediatrician Jasmin Furman at Hackensack University Medical Center's Institute for Child Development in February 2010. This is the first medical record in which a physician used the term "regression" to characterize the differences in M.W. after the vaccination, based on the history provided by Mrs. Wright. Pet. Ex. 16, p. 624. Specifically, she reported a regression in the use of words and eye contact after the immunization, the same losses she reported to Dr. Neubrander in December 2009. Pet. Ex. 25, p. 831. Mrs. Wright also reported the high fever, staring, and a possible seizure episode. Pet. Ex. 16, p. 624.

The history also reflected that M.W. began using words at about 12-14 months of age, but did not make much progress in vocabulary. M.W. was reported to have a current vocabulary of 20-50 words, most of which involved labels for "numbers, letters,

[46] The laboratory report did not reflect any association of these mutations with ASD. It indicated that the MTHFR enzyme was "responsible for creating the circulating form of folate" and that defects in the enzyme could "indirectly cause elevated homocysteine levels," which "have been associated with an increased risk of cerebrovascular disease, coronary artery disease, myocardial infarction, and venous thrombosis." Pet. Ex. 25, p. 858.

or incidental objects." Pet. Ex. 16, p. 624. ABA therapy had resulted in significant improvement. *Id*.

Doctor Furman diagnosed M.W. with autism, "with significant language communication deficits and overall low average cognitive abilities." *Id*., p. 626. She also noted a diagnostic impression of "[h]istory of high fever and change in alertness/level of consciousness following a childhood immunization in the past." *Id.*

On March 22, 2010, Dr. Gold considered M.W.'s condition and determined M.W.'s neurologic evaluation evidenced "a static encephalopathy of uncertain etiology." Pet. Ex. 17, p. 638; *see also id.*, pp. 636-37. When considering M.W.'s immunization history, history of seizures, and regression of milestones, Dr. Gold considered the possibility of a "post-vaccination encephalopathy." *Id.,* p. 638. Doctor Gold recommended a number of tests for heavy metals and porphyrins, according to a telephone message between Mr. Wright and someone at Bergen West Pediatrics. The health care provider (based on handwriting, likely M.W.'s pediatrician) advised Mr. Wright to have Dr. Gold order whatever specific tests he thought were appropriate. Pet. Ex. 8, p. 370.

In June of 2010, 11 months after M.W.'s Pentacel vaccination, Dr. Holahan performed a pediatric neurodevelopment evaluation. He summarized that M.W. had autism, that his regression began at 19 months, and that it was "temporally associated with vaccination." Pet. Ex. 20, pp. 807-09. Doctor Holahan's assessment was based on his observations at the consultation, not M.W.'s post-immunization symptoms. *Id.* Of note, Mr. Wright told Dr. Holahan that he thought he was "very similar to [M.W.] when he was young." Pet. Ex. 20, p. 808. Doctor Holahan summarized his findings regarding M.W. as "consistent with a diagnosis of static, neurological impairment, manifesting mild hypotonia and an autistic spectrum disorder. He is high functioning. He has excellent language skills. He is very bright. There was the regression at 19 months of age, temporally associated with the vaccination." *Id*., p. 809.

Doctor Gold referred M.W. to Dr. Wendy Chung for a genetic assessment. Her history reflected that M.W. knew the alphabet at 15 months of age, and had a vocabulary of 40-50 words at 18 months of age, and regressed after his 19 month vaccination. Pet. Ex. 22, p. 814. She reviewed the prior genetic testing. Her impression was that M.W. had "a history of normal development until approximately 19 months of age when he had a history of an intercurrent illness associated with vomiting and fever that occurred concurrently with an immunization. After that time he had developmental regression and a marked change in behavior." *Id*., p. 815. She doubted M.W. had genetic issues "based upon the initial history of normal development, regression, and then gains." *Id*., p. 816. She did not recommend any additional genetic testing, but suggested an MRI.

This appears to be the only medical evaluation, other than Dr. Neubrander's, in which the history provided reflected that M.W. was ill (i.e. vomited prior to the

immunization). Doctor Chung attributed the vomiting and fever to an illness, just as Dr. Wiznitzer did. *See* Pet. Ex. 22, p. 815; Tr. at 328.

A brain MRI was performed in November 2010. While no structural abnormalities were identified, there was "[s]lightly asymmetric FLAIR hyperintensity (left greater than right)" in the upper bilaterial periatrial regions. The report indicated that this could be due to asymmetric myelination, "mild sequela of prior infectious, inflammatory or ischemic etiologies" were possible explanations for the findings. Pet. Ex. 17, p. 642.

An overnight EEG was performed in October 2010. The attending neurologist concluded that it was a normal prolonged video EEG.[47]

F. Condition at the Time of the Hearing.

M.W. has received a variety of therapies, first through the early intervention system and later through the school system, which were augmented by privately arranged therapy and a "shadow" aide for school. *See, e.g*., Pet. Ex. 31, p. 1029-30; Tr. at 58-60.

At the time of the hearing, M.W. was six years old and enrolled in a kindergarten program at St. Catherine's school, where he participated in a mainstream classroom assisted by his own private classroom aide. Tr. at 60. Mrs. Wright reported that M.W. was able to read and write, solve math equations, and use internet search databases. Tr. at 61. Mr. Wright testified that "M.W.'s actually reasonably responsive, but he struggles very much verbally, in and out, and he is still impulsive and he still has some amount of the, 'Hey, you're not allowed to change what I'm doing.'" *Id.* at 136. Doctor Gold's December 2013 report described M.W.'s abilities and disabilities in greater detail, but in general observed that M.W. functioned well, but continued to struggle with communication and socialization. *See generally* Pet. Ex. 30.

## IV. Relevant Expert Opinions.

Two experts, Drs. Shafrir and Wiznitzer, testified at the hearing. Additionally, I considered Dr. Gold's opinions on the presence of a postvaccinal encephalopathy with regard to the Table injury requirement that an encephalopathy must persist for more than six months.

A. Doctor Gold.

No curriculum vitae was filed for Dr. Gold. According to his records, he practiced at the "Neurological Institute" in New York City. His signature block reflected that he

[47] An EEG, or electroencephalogram, records the electrical activity of brain cells. DORLAND'S at 600. It is used to evaluate a patient for possible seizures. *Id*.

was a professor of clinical neurology and clinical pediatrics at Columbia University. *See* Pet. Ex. 17, p. 640. Doctor Shafrir referred to him as "one of the giants of American Child Neurology." Pet. Ex. 27 at 976; *see also id*. at 983-94; Tr. at 268.

Doctor Gold, one of M.W.'s treating physicians, was originally scheduled to testify at the July 2014 hearing, but did not appear due to ill health. Tr. at 4. Mr. and Mrs. Wright testified about what Dr. Gold told them about M.W. (Tr. at 55-56; 134-35), but I did not place much reliance on second-hand recounting, when the reports and records speak for themselves. Two reports by Dr. Gold were filed as separate exhibits, Pet. Ex. 24, a neurological consultation conducted in December 2011, and a consultation from December 2013, Pet. Ex. 30. Other treatment records from Dr. Gold were filed as Pet. Ex. 17.

The December 9, 2011 report addressed causation quite summarily. Doctor Gold referred to M.W. as a child "with a previously diagnosed postvaccinal encephalopathy and a resultant static encephalopathy that is primarily manifested by deficiencies in communication and socialization, consistent with the diagnoses [sic] of an autism spectrum disorder." Pet. Ex. 24, p. 821. He did not explain who had arrived at that diagnosis or the basis for that conclusion. His December 2013 report began with the same statement. Pet. Ex. 30, p. 1026.

Doctor Gold's medical records, Pet. Ex. 17, answered the questions of who had made the diagnosis and the matters pertinent to the diagnosis. He recorded the following history:

> On July 6, 2009 at age 19 months [M.W.] was given a Pentace [sic] immunization which contained five organisms. Following the immunization and while returning home with his mother in her car [M.W.] convulsed for a brief period followed by five days of a febrile reaction with a temperature elevation as high as 102 degrees. Subsequently there was a loss of previously acquired skills, above all relative to communication and this was coupled with a loss of eye contact and a change in sleep patterns and diet.

*Id*., p. 634. He also recorded that M.W. used two-word phrases at 18 months of age. *Id*., p. 635. He noted that M.W. "was precocious and has an intense interest in letter and number recognition and this intense interest has continued to the present." *Id*. He did not specify whether this intense interest pre-dated the Pentacel vaccination.

Doctor Gold wrote in summary that M.W. had "evidence of a static encephalopathy of uncertain etiology. The history relative to the vaccination followed by a seizure and loss of previously acquired milestones suggests the possibility of a post-vaccination encephalopathy." Pet. Ex. 17, p. 638. He suggested an EEG to rule out a partial seizure disorder. *Id.*

After reviewing the MRI and EEG, Dr. Gold wrote the Wrights to inform them of the results. He noted that the EEG was normal. With regard to the MRI, Dr. Gold commented on the FLAIR hyperintensity, indicating that it was "in all probability . . . a nonspecific finding" but inflammation or ischemia could not be ruled out. Pet. Ex. 17, p. 640. He indicated that there was no evidence to suggest that M.W. had a progressive encephalopathy. *Id*.

Some anomalous pages appeared in Dr. Gold's records. Six pages were downloaded on November 19, 2010, from a website or blog called the "Age of Autism." Pet. Ex. 17, pp. 648-53. The initial page discussed the Food and Drug Administration approval for Pentacel. The pages contain a picture of a person or mask with a pentagram on the forehead, a baby with a middle finger raised, and a number of anti-vaccine comments. *See id*., p. 648. The remaining pages are the anti-vaccine comment string. *Id.*, p. 649-53.

At a December 2010 visit, Dr. Gold's opinions on the uncertain etiology of M.W.'s condition appeared to have changed. He wrote that at the initial visit, M.W. "showed evidence of a static encephalopathy with a history that was highly suggestive of a static encephalopathy secondary to a post-vaccination encephalopathy that was manifested by an autistic spectrum disorder." Pet. Ex. 17, p. 654. He subsequently recorded a diagnosis of "Postvaccinal Encephalopathy with a result static encephalopathy," and attributed M.W.'s ASD diagnosis to this encephalopathy. *Id.*, p. 661. Doctor Gold documented the continuing need for various therapies at his annual re-evaluations of M.W. *See, e.g., id*., pp. 656, 660.

B. Doctor Shafrir.[48]

Doctor Shafrir attended medical school in Israel and performed a pediatric residency there between 1983 and 1985. Pet. Ex. 28 at 985. He then did a second pediatric residence in New York at a hospital affiliated with Cornell University medical school. *Id*. He completed a residency and fellowship in pediatric neurology at Washington University Medical Center in St. Louis, MO, in 1991, followed by a residency in pediatric neurophysiology and epileptology at Miami Children's hospital which he finished in 1992. *Id*. He is board certified in neurology, with special qualifications in child neurology and clinical neurophysiology. *Id.* at 986. He was also board certified in pediatrics, but let that certification lapse in 1998. *Id*.; Tr. at 228.

[48] As noted earlier, Dr. Shafrir presented challenges as an expert witness. He began his testimony by scolding counsel and the court for asking questions about why the Wrights did not take M.W. to the emergency room if he was as "out of it" as they claimed he was. He informed us that our questions were not "relevant." Tr. at 232. Given that he was opining that M.W. experienced a Table encephalopathy, which requires that the vaccinee have an acute encephalopathy, defined as a condition 'that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred)" (42 C.F.R. § 100.3(b)(2)(i)), questions about M.W.'s condition and why he was not taken to the hospital would appear highly relevant. I add that at no point did questioning by either counsel or my own questions for the petitioners appear argumentative, condescending, or judgmental.

He is primarily a clinician, and is currently in an active private pediatric neurology practice in Baltimore, MD, where he sees patients five days a week. Pet. Ex. 28 at 987; Tr. at 228. He also teaches residents at Sinai Hospital, and is an Assistant Professor at the University of Maryland's School of Medicine. Pet. Ex. 28 at 987.

Most of Dr. Shafrir's initial expert report (Pet. Ex. 27) consisted of a thorough summary of the medical records and testing. *Id*. at 967-82. His opinions on causation encompassed only a little more than one page. *Id*. at 982-84.

He opined that M.W. met the Table encephalopathy criteria based on the presence of "a seizure associated with loss of consciousness and significantly decreased level of consciousness, which was independent of the seizure...[and an] encephalopathy [that] lasted more than 24 hours." Pet. Ex. 27 at 983. He asserted that M.W. "definitely" met "the criteria for significantly decreased level of consciousness" and that he had a chronic encephalopathy that persisted for more than six months, based on M.W.'s significant deficits. *Id*.

A supplemental report reiterated Dr. Shafrir's opinions that M.W. experienced a Table encephalopathy and his deference to Dr. Gold's opinion about a postvaccinal encephalopathy. Pet. Ex. 33 at 1041. Doctor Shafrir also opined that "[r]egressive autism is a chronic encephalopathy" and that M.W. had symptoms of autism for more than six months after the vaccination. *Id*. at 1041-42. He explained that he did not discuss the *Althen* factors in his initial opinion because he was so positive that M.W. met the Table criteria. Pet. Ex. 33 at 1042.

In his third expert report, he reiterated:

> It is still my belief that [M.W.] meets the criteria of injury on the Vaccine Injury Table for the DTaP, as applied to children above the age of 18 months. The lack of contemporaneous medical records describing the encephalopathy and the fact that [M.W.] was not hospitalized was explained by the parents in their affidavit, multiple phone calls to the pediatrician over the days following the vaccine and the poor records of the pediatrician as explained in my letter of July 17, 2013. The diagnosis of post vaccine encephalopathy was made in the one of the prime institutions in the United States by one of the giants of American child neurology, Dr. Gold.

Pet. Ex. 33 at 1041.

C. Doctor Wiznitzer.

Doctor Wiznitzer completed a combined undergraduate school and medical school program at Northwestern University, earning his medical degree in 1977. He

completed a residency in pediatrics and a fellowship in developmental disorders in Ohio, a fellowship in pediatric neurology at the Children's Hospital of Philadelphia, and a National Institutes of Health fellowship in higher cortical functions. Res. Ex. B at 1-2 (citations to the page numbers of the CV itself). He is board certified in pediatrics, neurology (with special qualification in child neurology), and neurodevelopmental disabilities. *Id.* at 5; Tr. at 321-22. He has published extensively in the areas of ASD, tuberous sclerosis, epilepsy and stroke, among others. Res. Ex. B at 13-24. He peer reviews papers for many medical journals and sits on the editorial board of three medical journals focused on neurology. *Id.* at 6. He regularly treats children with autism, and has been doing so since 1984. Tr. at 322-23. *See also* Dr. Wiznitzer's expert report, Res. Ex. A, at 1-2.

Doctor Wiznitzer opined that, because M.W. vomited prior to administration of the vaccination on July 6, 2009, any subsequent vomiting was due to an intercurrent illness. His fever lasted too long for a post vaccination fever, and must therefore be attributed to an intercurrent illness. He noted that there was no confirmation of a seizure event in the car, and that a later EEG was normal. Res. Ex. A at 14. He further opined that an encephalopathy severe enough to warrant hospitalization would interfere with oral nutrition and hydration, which, in turn would result in dehydration for which medical care would be necessary. *Id*. at 14-15. He thought that the failure to take M.W. to a physician during the period after his vaccination through October 21, 2009, reflected that M.W. did not have an abrupt regression, and that M.W.'s clinical presentation was consistent with the natural evolution of ASD. *Id*. He also noted that there were some areas of developmental concern prior to the immunization. *Id*. at 13-14. He based his opinion on the medical records. *Id*. He addressed the Table encephalopathy claim only in passing in his supplemental expert report, noting that there were some developmental concerns in the records prior to the vaccination at issue. Res. Ex. C. at 1, 4.

## IV. Evaluating Petitioners' Table Encephalopathy Claim

A. Severity Requirement—Hospitalization Test.

The closest question in this case is whether M.W.'s condition after the vaccination satisfied the requirement that any encephalopathy must be sufficiently severe so as to require hospitalization whether or not hospitalization occurred. *See* 42 CFR 100.3(b)(2)(i). M.W. was not hospitalized; thus I must determine whether he was sufficiently affected that hospitalization was "required." The term "required" must mean something other than "necessary to save the child's life"; otherwise, entitlement to compensation in the non-hospitalization cases would be limited to those in which the child died. I interpret the term as requiring sufficient severity of illness or injury that presentation at a hospital should result in some form of medical monitoring or being "admitted for observation." It does not require that medical intervention be necessary in order to save a child's life.

Doctor Wiznitzer opined that a child capable of drinking and urinating would not meet the Table's severity requirement. *See* Tr. at 328, 345. This opinion was consistent with the advice given by the staff at Valley Pediatrics, that there was no need to bring M.W. back to the practice or to the emergency room because he was capable of drinking and producing urine. I note, however, that many individuals who are hospitalized are capable of drinking and producing urine. The fact that M.W. was drinking from a bottle (and there was no testimony that he was sitting up and drinking from a cup), and taking in enough liquid to produce urine does not preclude the necessity for hospitalization.

Doctor Wiznitzer conceded that a competent pediatrician who received the information Mrs. Wright said she conveyed would tell her to return to the office or go to the emergency room. Tr. at 410-11. He also conceded that the lack of ability to drink and produce urine did not appear as a factor anywhere on the Vaccine Injury Table. Tr. at 390.

Had Mrs. Wright shown up at an emergency room describing what happened in the car, within a few hours of a vaccination, would she summarily have been turned away or would M.W. have been admitted for observation? During the first 24 hours after the brief seizure in the car, his parents described an altered mental state. While there are no medical records reflecting what transpired after the vaccination, other than Dr. Leifer's very brief note, there are records of calls going back and forth between the Wright home and the pediatric practice. The repeated calls by the practice are sufficient corroboration that M.W. was experiencing something out of the ordinary. The pediatric practice's failure to document what transpired during the calls should not be held against the Wrights. I note that the others Mrs. Wright talked to during the first week after M.W.'s vaccination used the term "convulsion" when describing what happened in the car. This is not an incident invented out of whole cloth.

I questioned Mr. Wright closely about why he thought M.W.'s condition was severe, yet did not take him to a hospital. I questioned Mrs. Wright about the same issue. Their explanations that Mrs. Wright wanted to do so and that Mr. Wright told her she was, in effect, pregnant and hysterical, were given independently, in that Mr. Wright was sequestered during Mrs. Wright's testimony. Their testimony was not interlocking: Mrs. Wright attempted to explain or minimize Mr. Wright's "the doctor must be right" reaction, while Mr. Wright admitted that he had been inappropriately tunnel-visioned about what was happening. Both of Mrs. Wright's aunts confirmed her testimony that she wanted to take M.W. to the emergency room and that she was second-guessing or at least seeking an opinion about the pediatric practice's advice against doing so. What rang clearly true in her testimony is the degree of concern she felt about M.W.'s condition and how differently he was behaving, compared to his usual behavior.

The definitional criteria for encephalopathy found in the QAI are subparts to the hospitalization requirement. I thus conclude that the hospitalization requirement is not entirely independent of the symptoms reflected in those subparts, but a requirement to

emphasize the severity of the symptoms needed to constitute an acute encephalopathy. I have previously held that transient or reduced eye contact—the lack of eye contact often seen in ASD—is not sufficient, standing alone, to meet the "decreased or absent eye contact" requirement of the QAI because that lack of eye contact is not sufficient to meet the hospitalization requirement. *Miller v. Sec'y, HHS,* No. 02-235V, 2015 WL 5456093, at *38 (Fed. Cl. Spec. Mstr. Aug. 18, 2015); ***Blake v. Sec'y, HHS,*** No. 03-31V, 2014 WL 2769979, at *11-12 (Fed. Cl. Spec. Mstr. May 21, 2014), *motion for reconsideration denied,* 2014 WL 7331948 (Fed. Cl. 2014); *Mooney v. Sec'y, HHS,* No. 05-266V, 2013 WL 3874444, at *8 (Fed. Cl. Spec. Mstr. July 3, 2013). Here, there was far more than transient or reduced eye contact; the testimony was that M.W. was "out of it," "spacey," "staring into space," "physically and mentally somewhere else," "minimally responsive" to "nonresponsive, "catatonic," and "basically immobile."

In the Revision of the Vaccine Injury Table, 60 Fed. Reg. 7,685, 7,687 (Feb. 20, 1997) (preamble to final rule) the drafters explained that they "did not intend that hospitalization be viewed as an absolute requirement to establish an acute encephalopathy, but rather as an indicator of the severity of the acute event." I conclude, based on the facts of this case, that M.W.'s acute event was sufficiently severe so as to meet the hospitalization requirement.

B. The Acute Encephalopathy Requirements.

Doctor Shafrir testified that the basis for his opinion that M.W. had suffered an acute encephalopathy was that his condition satisfied the two criteria under the Table's definition of encephalopathy for adults and children 18 months of age or older: (1) a significantly decreased level of consciousness, which is independent of a seizure and cannot be attributed to the effects of medication; and (2) a seizure associated with loss of consciousness. Tr. at 290-91; 42 C.F.R. § 100.3(b)(2)(i)(B)(2-3). He agreed that the evidence of this was primarily found in petitioners' affidavits. Tr. at 291; Pet. Ex. 27 at 983-84.

Respondent's counsel raised the issue of whether the seizure event could have been an absence seizure during her cross-examination of Dr. Shafrir. *See* Tr. at 292. An absence seizure is specifically excluded as a seizure event qualifying as a Table encephalopathy. *See* § 100(b)(4). An absence seizure is defined as a seizure "consisting of a sudden momentary break in consciousness of thought or activity, sometimes accompanied by automatisms or clonic movements, especially of the eyelids." DORLAND'S at 1688. Doctor Shafrir testified that a person having an absence seizure would not "respond at all. Absence seizures don't respond." Tr. at 292.

What Mrs. Wright described when she looked into the rear seat after M.W. did not respond to her voice (M.W.'s head tilted to the side, eyes rolled back, and shaking) is not consistent with the DORLAND'S definition of absence seizure. I thus conclude that, whatever type of seizure M.W. experienced in the car, it was not an absence seizure.

My factual findings in Section III above reflect that M.W.'s condition satisfied all of the requirements for an acute encephalopathy. Although M.W. slept long and hard on July 6 and 7, his sleepiness was not a basis for my conclusion regarding the presence of an acute encephalopathy. Rather, it was the lack of responsiveness to his family when he was awake. Even after the acute events of July 6-7, 2009, M.W. did not return to baseline. Ms. Sierra's testimony about his response to her on Thursday, July 8, when he was recovering, and his behavior on July 9, when he was able to return to her care reflect some degree of residual symptoms. Both are corroborative of the parents' testimony about how ill he was earlier. Also corroborative is the fact that the pediatric practice still thought it necessary to call three times on July 7 and twice on July 9 to check on M.W.'s condition. Based on my years of experience as a special master, I noted that the pediatric practice's calls were highly unusual (and well-documented by the telephone records (Pet. Ex. 26, pp. 961-62)) and had to reflect some heightened degree of concern about M.W.'s condition.

Doctor Wiznitzer also testified that the events in the car might have been precipitated by M.W.'s need to vomit due to illness. However, what Mrs. Wright described was not the attempt to control vomiting or the need to vomit.

Doctor Wiznitzer's testimony may have been shaped by his assertion that one hour post vaccination was simply too soon biologically for an immunization to cause an event. This testimony was highly relevant to the actual causation claim, but not at all relevant to the Table injury claim. The Secretary, HHS, has been delegated the authority to promulgate regulations to modify the Vaccine Injury Table. See § 14(c)(1). The Secretary determined that the appropriate period for a Table encephalopathy to manifest after receipt of a pertussis vaccination is 0-72 hours. Doctor Wiznitzer's opinion that it is biologically implausible for a seizure to manifest in one or two hours after a tetanus-containing vaccination is, *in the context of a Table injury*, simply irrelevant.[49] To the extent that this biological plausibility argument was intended to demonstrate that any seizure was more likely than not caused by an illness rather than the vaccine, I will afford the testimony little weight. The Secretary writes the rules for a Table injury, and her expert witnesses cannot rewrite them within the confines of a vaccine injury proceeding.

Although Dr. Wiznitzer was critical of the lack of detail reflected in the records of the physicians who recorded the history that M.W. had convulsed, I note that Dr. Furman concluded from what Mrs. Wright told her that M.W. had decreased alertness and a diminished level of consciousness post vaccination. I also observe that, in a perfect world, when the treating physicians write patient contact notes with the expectation that they will be parsed in the "Vaccine Court," such uncertainties and

[49] In testifying on cross examination about this issue, Dr. Wiznitzer was asked why the Table used the 0-72 hour time frame, and he responded" "you'd have to ask the people who developed the Table," maintaining that it would be "biologically impossible" for something to happen immediately after a vaccination. Tr. at 396.

ambiguities will not exist. This is not that world. As a frequent witness in such proceedings and, more importantly, a highly respected researcher in ASD and other neurological conditions arising in the pediatric population, Dr. Wiznitzer understands the importance of eliciting careful and precise histories. Busy clinicians may not.

Based on the record as a whole, and in accordance with my earlier factual findings, I find that M.W.'s condition met the requirements of an acute encephalopathy as set forth in the Vaccine Injury Table. *See Riggs v. Sec'y, HHS*, 40 Fed. Cl. 440 (1998) (reversing the special master's decision that the infant had not suffered a Table encephalopathy and finding that symptoms including sleeping 60 out of 72 hours after vaccination, waking only on prompting, and disinterest in food constituted the significantly decreased level of consciousness and inconsistent or absent responses to external stimuli necessary to demonstrate a Table encephalopathy).

C. Chronic Encephalopathy.

Both Drs. Gold and Shafrir opined that, post vaccination, M.W. had an encephalopathy. Doctor Gold saw M.W. for the first time more than six months after the vaccination, and as late as 2013, still opined that he had a postvaccinal encephalopathy, resulting in ASD symptoms.

Even Dr. Wiznitzer conceded that it would be possible, albeit rarely, for someone who had experienced an encephalopathic event that would meet the definition of a Table encephalopathy to thereafter manifest sufficient criteria to fall under the autism spectrum. Tr. at 368. He thereafter qualified his answer to reflect that he would expect to see evidence of an acquired injury to the brain on neuroimaging. Tr. at 370. Although M.W.'s MRI was read as normal, the hyperintensity observed was consistent with "mild sequela of prior infectious, inflammatory or ischemic etiologies." Pet. Ex. 17, p. 642. I note that it was after the MRI and genetic testing that Dr. Gold changed his opinion on causation from an unknown etiology to a postvaccinal event.

Doctor Wiznitzer also testified that even if M.W. had been hospitalized with an acute encephalopathy and thereafter developed ASD, he would not attribute the ASD to the encephalopathy. Tr. at 374-75. He was cross-examined about a medical journal article filed along with his expert report,[50] which noted that about five percent of newborns with encephalopathy were later diagnosed with an ASD. Tr. at 379-80; Johnson, Res. Ex. A, Tab 1, at 1189. Doctor Wiznitzer did not disagree with the numbers, but he observed that the article did not discuss cause, simply an association. Tr. at 380-81.

Doctor Wiznitzer testified that the failure to take M.W. to a doctor over the summer did not mean that M.W. was not encephalopathic, and he thought that the

[50] C. Johnson, et al., *Identification and Evaluation of Children with Autism Spectrum Disorders*, PEDIATR. 120:1183-1215 (2007), filed as Res. Ex. A, Tab 1 [hereinafter "Johnson, Res. Ex. A, Tab 1"].

parental conflict about whether M.W. needed to be seen was an explanation for why he was not seen earlier than October. Tr. at 407-08. However, he thought the descriptions of the relatively rapid onset of symptoms over the summer were affected by recollection bias, and that they likely occurred more slowly. Tr. at 408.

However, the evidence in the record supports Mr. and Mrs. Wright's testimony that M.W.'s eye contact never returned to baseline after the events of July 6, 2009. He continued to have poor response to his name, and seemed to be in his own world.

D. Alternate Cause.

Once petitioners establish a prima facie case for a Table encephalopathy, the burden shifts to respondent to establish, by preponderant evidence, an alternate cause for M.W.'s condition. Doctor Wiznitzer, relying largely on two pieces of evidence, concluded that an unspecified gastrointestinal illness constituted an alternate cause for M.W.'s condition. First, he pointed to the vomiting that occurred prior to the vaccination. Second, he noted that M.W. got better when he was no longer febrile, and that a febrile illness caused the change in his activity level. He thus concluded that M.W. "did not suffer a post-vaccine table encephalopathy." Tr. at 345. He pointed to the fact that M.W. drank as an act that demonstrated responsiveness to his environment. Tr. at 345-46. He observed that M.W. "complained" when his temperature was going up, let his parents "know that he was in discomfort, that something was bothering him." Tr. at 346. He also testified that M.W. went to bed, got out of a crib in the middle of the night, walked upstairs to the steps, sat down, rubbed his neck and looked for an adult, as evidence that M.W. was not encephalopathic. Tr. at 346-47. Doctor Wiznitzer testified that M.W.'s "change in behavior that he manifested immediately after the vaccination was due to an intercurrent illness." Tr. at 328. Dr. Wiznitzer also noted that "when the fever improved, so did he." *Id.* He further expressed his lack of "surprise" that "a child with a febrile illness…didn't have a lot of energy and…slept a lot." *Id.*

Either Dr. Wiznitzer heard the testimony differently from how I heard it (and what the transcript reflected) or he was dramatizing for effect.[51] M.W. did not climb out of a crib, but rather a bed with low rails. In her seventh month of pregnancy, Mrs. Wright would not have climbed into a crib to spend the rest of the night of July 7-8 with M.W. He did not walk upstairs—in fact, based on the testimony, Mrs. Wright was asleep and did not notice how M.W. got to the landing at the top of the stairs. He could have

[51] I do not intend to imply that Dr. Wiznitzer was deliberately misstating the evidence. Rather, I think he had concluded when he wrote his initial expert report that this was not a Table case, and his recollection of the evidence and the inferences he drew from that evidence were affected by his conclusion. It appeared from some of Dr. Wiznitzer's testimony that he doubted the existence of any Table encephalopathy from a DTaP vaccination. *See* Tr. at 363-64. I have the utmost respect for Dr. Wiznitzer as an expert and as an expert witness, but sometimes his testimony, particularly on cross-examination, is more partisan than it should be.

crawled there.[52] The evidence was that M.W. did not walk at all in the first two days after his vaccination. Mr. Wright's very brief comment that M.W. might have walked to the bathroom was quickly retracted as he remembered that M.W. was 19 months old and still in diapers.

Doctor Wiznitzer made it sound as though M.W. deliberately went looking for his parents and actively sought his mother's attention. I find her account of what happened that night more consistent with a child with some degree of delirium. And, even if the events had happened as Dr. Wiznitzer described, these incidents, including the point at which M.W. got out of his bed, occurred well more than 24 hours after M.W.'s seizure, and thus outside the period a Table encephalopathy must persist.

I have carefully searched the records in this case and have re-read the transcript on several occasions, but I cannot find any evidence that M.W. complained during the four days before he went back to his babysitter, other than perhaps in the fit he threw in the doctor's office. I find it far more likely that this fit was a complaint about being where he was and recognizing the office as a place where strangers examined him and gave him shots, rather than a complaint about being in discomfort. I note that his level of agitation got worse when examined, suggesting that it was stranger anxiety or the knowledge of the impending vaccination that was most likely responsible for that escalation.

Doctor Wiznitzer conceded on cross examination that a child might throw up in a doctor's office for reasons other than being ill, although he caveated his answer by saying it depended on the child's personality and on the clinical course at the time, intimating that M.W.'s clinical course was consistent with illness. Tr. at 390-91.

However, Dr. Leifer examined M.W. after he vomited and found no evidence that he was acutely ill. A doctor about to order administration of a vaccination, faced with a child who had recently vomited, would likely be in a heightened state of concern that the child was well enough to receive a vaccination. I thus find Mrs. Wright's testimony about the degree of questioning by Dr. Leifer to be well corroborated. I am satisfied that Dr. Leifer conducted a full examination, and found no signs of acute illness.

Second, Dr. Wiznitzer talked about the infection being gastrointestinal in nature, but there was no evidence that M.W. experienced frequent vomiting and no evidence at all that he had any diarrhea. While a child may have a gastrointestinal problem involving either vomiting or diarrhea, the two symptoms appear frequently together in the hundreds of medical records I have reviewed.

[52] M.W. still crawled, occasionally at least, as Ms. Sierra testified that he usually crawled around on the floor after his sister. Tr. at 210.

After the vomiting episode in the car (which was likely post-ictal in nature), there was no evidence that M.W. vomited frequently in the next two days.[53] He vomited after the event on the stairs, but at that point, he had quite a high fever, according to Mrs. Wright. It was not the vomiting that concerned his parents; it was M.W.'s lack of response to them and his surroundings.

Doctor Wiznitzer attributed M.W.'s behavior to fever and the fever to illness. However, M.W. did not get better when given Tylenol. According to his parents, he was being dosed with Tylenol or Motrin regularly, but remained "spaced out" and unresponsive for most of the first two days after his vaccination. Thus fever was not involved in causing the underlying behavior, although whatever caused the fever might have been a factor.

To his credit, Dr. Shafrir agreed that an illness that could cause vomiting prior to vaccination could also cause vomiting and convulsing; that a high temperature such as one from an illness could cause vomiting, and that illness could cause "a couple of days of lethargy" and abnormal sleepiness. Tr. at 293-94.

But that was not the entirety of M.W.'s presentation. These were not first-time parents presented with a first illness of a child. Mrs. Wright came from a large family and had frequent contact with babies and children, and M.W.'s older sister undoubtedly experienced childhood illnesses. Petitioners described something profoundly different in M.W.'s appearance and symptoms. M.W. may well have had some type of intercurrent illness, but he did not have a high fever or episodes of frequent vomiting at the time his mental and cognitive processes were at their lowest ebb. The high fever came afterwards. M.W. simply presented with more severe neurological symptoms than would normally be seen in a gastrointestinal illness, and lacked the high temperature that might cause such symptoms at the time when they were most prominent. The high fever did not present until the time of the event on the stairs, and likely produced some of the delirium-like symptoms that occurred at that point.

Finally, respondent contends that M.W.'s pre-vaccination symptoms preclude a finding that his post-vaccination encephalopathy (ASD) is the result of his acute encephalopathy. Evidence that M.W. was not neurologically normal prior to the vaccination is extremely sparse. There were no concerns about his language development expressed in any of his pediatric records. The "well-child" aspects of his July 6, 2009 appointment were not documented at all, but if Mrs. Wright had expressed any concerns about his development, Dr. Leifer should have reflected them. While I do not accept the reports about the extent of his vocabulary pre-vaccination to include 20-

[53] To the extent that Mr. Wright's and Mrs. Wright's testimony about when and how often M.W. vomited differ, I will accept Mrs. Wright's accounts as more likely to be correct as she was the parent most actively involved in M.W.'s care that week. Mr. Wright was home, but working from home, and thus did not spend the same amount of time with M.W. that his mother did. Similarly, their reports about fever differed, and I accept her accounts as more accurate.

50 words (even counting each letter of the alphabet and each number he could repeat as a word), no one expressed any concern about his language skills pre-vaccination. I find the contemporaneous records more likely reflected the extent of M.W.'s communicative vocabulary at 15 months of age, which was two words in addition to the names of his three family members. M.W. may well have been able to recite and identify letters of the alphabet at or near 15 months of age, but he was not communicating when he was doing so.[54]

According to testimony, prior to the vaccination M.W.'s parents observed him playing with his sister, pointing to things in order to gain his parents' attention, and following simple directions. Tr. at 11. Mr. Wright described M.W. as playful and attentive with others prior to 19 months. Tr. at 110-11. Ms. Valentine testified that in M.W.'s first 19 months of life, he interacted socially with others by running towards them, giving hugs, pointing to things, and playing with constructible toys. Tr. at 178; *see also* Pet. Ex. 89 at ¶5. She made these observations while M.W. stayed at her home overnight or during the day every three to four weeks. Tr. at 178, Pet. Ex. 89 at ¶4.

Ms. Donna Sierra, M.W.'s babysitter, began caring for him when he was six weeks old. Tr. at 205. Before M.W. was 19 months old, Ms. Sierra testified that he would interact with his siblings by seeking their attention by crawling towards them. Tr. at 206; *see also* Pet. Ex. 88 at ¶ 3.[55]

The strongest evidence that M.W.'s development may not have been optimal prior to the vaccination is in the M-CHAT Mrs. Wright completed at the July 6, 2009 visit to Valley Pediatrics. It reflected that M.W. engaged in pretend play only "sometimes." and that he understood what people said "sometimes" as well. Pet. Ex. 5, p. 338. "Sometimes" does not mean that the skills were absent and that he could not perform them; it means that M.W. did perform them, but not all the time. After the vaccination, he did not perform them at all. The only evidence that M.W.'s eye contact was not "optimal" was in Dr. Nalven's evaluation. Pet. Ex. 15, p. 617. Petitioners denied that Mr. Wright made this comment (Tr. at 93, 162), which did not, in any event, specify whether the lack of optimal eye contact existed before or after the vaccination. Mr. Wright testified that M.W.'s eye contact prior to his July 2009 vaccination was "[u]nremarkable in the sense that it was normal." Tr. at 142.

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[54] Some of the histories in later medical records also reflect a vocabulary of 40-50 words prior to the Pentacel vaccination, but they do so in the context of labeling letters and numbers, rather than the use of words in communication. *See* n.45 and accompanying text; *see also* Pet. Ex. 15, p. 617 (observing M.W.'s use of language to label rather than to communicate); Pet. Ex. 20, p. 809 (indicating that M.W. has excellent language skills). It does not appear that those physicians who elicited this history thought that M.W.'s labeling of letters or numbers constituted communicative effort, in that he was reported as still doing that labeling after the vaccination, but the physicians and speech therapists did not count such "words" as part of M.W.'s vocabulary.

[55] I note that when M.W. was 19 months old, he had only one sibling. His younger brother was born in September 2009. *See* Pet. Ex. 13, p. 606 (listing younger brother's birthdate).

I find that M.W.'s development was, more likely than not, within normal limits prior to his July 6 vaccinations. Thereafter, it deteriorated, and eventually he received an ASD diagnosis. I am not required to find that the vaccination actually caused that diagnosis. Rather, I find that the neurological and behavioral symptoms he displayed for well more than six months after the vaccination constituted a chronic encephalopathy, which meets the diagnostic criteria for ASD.

Many, if not most, cases of ASD constitute a chronic encephalopathy. However, only rarely do the symptoms of ASD follow an acute encephalopathy, in which some of those symptoms are part of the acute encephalopathic picture. This case is one of those rare events. Because M.W. had an acute encephalopathy meeting the Table requirements, followed by a chronic encephalopathy, a presumption of causation attaches regarding his current condition.

*I emphasize again that this is NOT a case in which a judicial determination has been made that vaccines actually caused a child to develop ASD.* Since I was assigned to the "autism docket" in early 2007, as one of the three special masters to hear the OAP test cases, I have had approximately 1800 cases alleging vaccine causation of ASD on my docket. In my nearly nine years on this autism docket, I have not read or heard any reliable evidence in any case, including this one, that vaccines can or do cause ASD.

## V. Conclusion.

M.W. experienced an acute encephalopathy, with onset beginning within two hours of his Pentacel vaccination. The acute encephalopathy persisted for more than 24 hours. Although there is some evidence of an intercurrent illness, that evidence does not reach the level of preponderant evidence of alternate cause. M.W. never returned to baseline after the vaccination. He has a chronic encephalopathy which has persisted for over six months.

Petitioners are therefore entitled to compensation for M.W.'s condition as a Table encephalopathy. A damages order will be issued shortly.

**IT IS SO ORDERED.**

**s/Denise K. Vowell**
Denise K. Vowell
Special Master